Table of Contents

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII. Pharmacists

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LIII. Pharmacists

Chapter 1. Introduction

§101. Preamble

A. Pursuant to the authority granted by R.S. 37:1182, and in the interest of promoting the public health, safety, and welfare, the following rules and regulations are hereby adopted by the Louisiana Board of Pharmacy (board).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2075 (October 2003), effective January 1, 2004.

§103. Pharmacy Board Organization

A. Board Officers

1. President. The president shall preside at all board meetings.

2. Vice-Presidents. In the absence of the president, the vice-presidents shall preside in descending order at all board meetings.

3. Secretary. The secretary shall conduct the nomination procedure for board candidates and report the results of the balloting to the governor for his appointments.

B. Election

1. General Election. The board shall annually elect officers from its membership.

2. Special Election. The president may call a special election of the board to fill vacancies of elected officers.

C. Officers' Terms. Officers elected by the board shall serve one-year terms and their terms shall end upon the election of their successors. An officer elected to a vacant position shall serve for the remainder of that term, at which time an election shall occur commensurate with the annual election.

D. Per Diem. A per diem, as authorized by R.S. 37:1178, is defined as compensation to be received by a board member for each day of service while attending regular or called board meetings, while attending to official business of the board, or while attending a board related or board sanctioned conference, including travel days for members to and from these meetings, conferences, and related business. This per diem shall not serve as reimbursement for meals, lodging, and other expenses incurred as a result of these meetings, conferences, and related business.

E. Board Budget. The board is a self-sustaining body that shall generate sufficient revenues funded by fees, appropriations, and/or assessments in order to maintain efficient operations.

1. Administrative Costs. The board may assess administrative costs as it deems necessary to facilitate the proper implementation of its rules and regulations.

2. Annual Operating Budget. The board has the responsibility to perfect an annual operating budget.

3. Annual Capital Budget. The board has the responsibility to establish a capital budget, when applicable.

F. Executive Director. The executive director shall carry out functions of the board relative to its statutory requirements and other duties as defined by the board. With the board's approval, the executive director serves as the appointing authority and may appoint additional employees for professional, clerical, and special duties necessary to carry out the board's functions and may establish standards for the conduct of employees.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2075 (October 2003), effective January 1, 2004.

§105. Board Procedures

A. All board procedures and operations shall adhere to the Administrative Procedure Act, R.S. 49:950 et seq., the Open Meetings Law, R.S. 42:4.1 et seq., and the Public Records Act, R.S. 44:1 et seq.

B. Order. *Robert's Rules of Order* shall govern all proceedings unless otherwise provided.

C. Public Comments. A public comment period shall be held during each board meeting.

1. Persons desiring to present public comments shall notify the board chairman or executive director no later than the beginning of the meeting. However, to assure that an opportunity is afforded to all persons who desire to make public comments, the chairman shall inquire at the beginning of the meeting if there are additional persons who wish to comment. The chairman shall allot the time available for the public comments in an equitable manner among those persons desiring to comment, limiting each person to a maximum of three minutes, with the total comment period not to exceed 30 minutes. Each person making public comments shall identify himself and the group, organization, company, or entity he represents, if any.

2. Unless otherwise provided by law, public comment is not part of the evidentiary record of a hearing or case unless sworn, subject to cross-examination, offered by a party as relevant testimony, and received in accordance with the Administrative Procedure Act, R.S. 49:950 et seq.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2076 (October 2003), effective January 1, 2004.

§107. Board Committees and Subcommittees

A. Board committees are working bodies created by the board comprising members appointed or removed by the president to address and deliberate specific pharmacy matters referred by the board for specified periods consisting of the following.

1. Standing Committees. Standing committees are permanent bodies and are created by the board comprising members appointed by the president with the duty to address and deliberate specific subject matters referred by the board.

2. Special Committees. Special committees are appointed by the president for a particular period to address or deliberate special matters.

3. Board Subcommittees. Board subcommittees are created by the board comprising members and ex-officio non-voting members appointed by the president that are ancillary to a standing or special committee to address or deliberate a limited committee subject matter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2076 (October 2003), effective January 1, 2004.

§109. Standing Board Committees

A. Executive Committee. The executive committee, comprised of the president, vice-presidents, and secretary shall function to address interim administrative board matters that require immediate attention between regularly scheduled board meetings.

B. Regulation Revision Committee. The regulation revision committee, consisting of at least three board members appointed at the discretion of the president, shall function to preliminarily draft rules, regulations, and policies to be considered by the full board for promulgation and/or resolution or order.

C. Reciprocity Committee. The reciprocity committee, consisting of at least three board members appointed at the discretion of the president, shall function to document the qualifications, compliance, and credentials of reciprocity candidates.

D. Impairment Committee. The impairment committee, consisting of at least three board members appointed at the discretion of the president, shall function to study, recognize, address the need to identify, and monitor the recovery of impaired persons in order to protect the public and the practitioner. Additionally, the impairment committee shall function to investigate, review, and interview impaired or allegedly impaired persons practicing or assisting in the practice of pharmacy and tender findings and recommendations to the board.

E. Violations Committee. The violations committee shall consist of at least three board members appointed at the discretion of the president. Board-designated staff shall preliminarily determine the disposition of complaints and alleged offenses. Thereafter, the violations committee shall function to receive complaints, receive staffs' reports, and evaluate and review findings. The disposition of alleged offenses shall be determined by conducting an informal inquiry conference, an interlocutory hearing, and/or referring the matter to special counsel for formal hearing by the full board.

F. Reinstatement Committee. The reinstatement committee, consisting of at least three board members appointed at the discretion of the president, shall function to receive complaints, receive staffs' reports, evaluate and review findings, interview applicants, deliberate, and tender recommendations to the full board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2076 (October 2003), effective January 1, 2004.

§111. Official Journal

A. The official journal of the board is the *Louisiana Board of Pharmacy Newsletter*. The newsletter may be used in administrative hearings as proof of notification to pharmacists, interns, pharmacy technicians, pharmacy technician trainees, and holders of pharmacy permits.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004).

Chapter 3. Board Hearings

§301. Board Hearing Procedures and Jurisdiction

A. Person. The board has jurisdictional authority over the person practicing pharmacy, assisting in the practice of pharmacy, operating a pharmacy, or otherwise licensed, registered, certified, or permitted by the board. A person is as defined in R.S. 37:1164(33) of the Pharmacy Practice Act.

B. Subject Matter. The board has jurisdiction over any subject matter related to the practice of pharmacy or any other matter regarding the dispensing or selling of prescription drugs in a safe manner so as not to endanger the public health, safety, or welfare.

C. Board Authority. The board has authority to adopt rules pursuant to the Pharmacy Practice Act, R.S. 37:1161 et seq., and the Administrative Procedure Act, R.S. 49:950 et seq., regarding due process disciplinary hearings.

D. Venue. A due process hearing shall convene in a designated Louisiana parish at a regularly called board meeting.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

§303. Summons

A. A summons shall represent a complaint of an alleged violation directed to a respondent.

B. Hearing Notice. The board shall initiate a hearing by issuing a notice summons. The notice summons shall be forwarded to the respondent commanding his presence to appear before the board for a due process hearing setting forth the following.

1. Name. The notice shall include the respondent's name and address.

2. Time. The notice shall state the designated time, date, and place.

3. Allegation. The notice shall recite the alleged violation(s) establishing a cause of action and the nature of the hearing.

4. Authority. The notice shall make references to specific board, state, or federal statutes, regulations, rules, policies, or code of ethics involved in the alleged violation(s).

5. Citation. The notice shall cite legal or jurisdictional authority constituting an alleged violation(s).

6. Documents. The notice may include supporting documents, reports, and/or other relevant material.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

§305. Service

A. Method. Service of a summons shall be made either by regular, registered, or certified mail, with a return receipt requested, or board or court designated process servers confected by tendering the summons to the respondent personally or domiciliary at the last known address.

B. Time. Service shall be made at least 30 days prior to the date of the hearing as per R.S. 37:1245.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1245.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

§307. Default Proceedings

A. The board may proceed with a hearing in the event the respondent fails to appear after due notice was perfected or a diligent effort had been made to perfect service on the respondent at the last known address of record.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

§309. Joinder

A. Several complaints may be joined or incorporated and the respondents may be joined in the same or similar complaints based on the same or similar acts or transactions that are connected in a common plan or scheme.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

§311. Consolidation

A. Hearings may be held jointly to assure a fair due process hearing. Any alleged violations may be consolidated for an administrative hearing of respondents.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

§313. Severance

A. A severance of complaints is permitted when a fair due process hearing will not be satisfied. Otherwise, complaints may be heard jointly.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

§315. Motions

A. Hearing Motions. Motions are directed to the board or presiding officer for particular relief or action before, during, or after a hearing and shall be in writing when applicable, and allege specifically the grounds upon which the relief is based, and filed with the board five days before hearing or within 10 days post-hearing or timely filed during the hearing. At an appropriate time to be decided by the hearing officer, oral or written motions may be directed to the presiding hearing officer during a hearing. Hearing motions are directed to the presiding hearing officer and disposed of appropriately.

B. Continuance Motions

1. Postponement Motions. The board may grant or deny a continuance based upon critical or extenuating circumstances that could jeopardize a fair and expeditious due process hearing.

2. Time. Continuance motions shall be filed in writing at least five days prior to the scheduled hearing with specific grounds for postponement. This requirement may be waived by the board under emergency circumstances.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

§317. Recusation

A. A board member or special counsel may be recused by one's own motion because of an inability to contribute to a fair and impartial hearing or may be recused by a majority vote of the board members present based on the following grounds:

1. prejudicial or personal interest in a case that might prevent one from participating in an impartial hearing;

2. the board may recuse the presiding administrative hearing officer on his own motion or he may be disqualified based upon his own inability to contribute to or conduct an impartial hearing by the respondent filing an affidavit of specific grounds at least five days prior to the scheduled hearing.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

§319. Sequestration

A. Upon request by either respondent or special counsel or by direction of the hearing officer, witnesses shall be sequestered and not allowed in the hearing chambers or permitted to discuss their testimony with other witnesses.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

§321. Sanction Guidelines

A. The sanctions imposed by the board pursuant to R.S. 37:1241 of the Pharmacy Practice Act shall be based on the following guidelines.

1. Nature. The nature or seriousness of the violation.

2. Degree. The degree of culpability, knowledge and/or intent, or the responsibility to have knowledge.

3. Scope. The scope of circumstances involved.

4. Demeanor. Honesty and truthfulness of respondent.

5. History. History of prior offenses.

6. Sanctions. Prior sanctions.

7. Cooperation. Willingness of respondent to comply with applicable laws and regulations and avoid future violations.

8. Sufficiency. Sanctions are sufficient to remedy the problem.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

§323. Administrative Investigation

A. Upon the receipt of a written complaint, board staff shall initiate and conduct an investigation.

1. Grounds. The investigative report shall be reviewed by board-designated staff and forwarded to the violations committee or legal counsel to determine sufficient grounds for proceeding either informally or formally.

2. The report shall include:

a. respondent's name and address; and

b. a concise statement of facts and circumstances indicating the basis of the routine or specific complaint or cause of action; and

c. supporting documents and/or materials.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

§325. Violations Committee

A. Purpose. Board-designated staff shall receive reports and complaints and review and evaluate findings to determine the nature and disposition of the alleged violation(s). The alleged violation(s) may then be directed to:

1. violations committee for informal hearing;

2. violations committee for interlocutory hearing; and/or

3. special counsel for institution of a formal administrative hearing.

B. Guidelines. If determined appropriate by board-designated staff, the violations committee shall receive and review complaints and determine the disposition of the pending matters based on the following.

1. Seriousness. The seriousness of the alleged offense.

2. Degree. The extent of the alleged violations.

3. History. The history of prior violations.

4. Record. Prior sanctions.

5. Cooperation. Willingness to obey the prescribed laws and regulations.

6. Deterrent. Consider the sanctions as a deterrent to future violations.

7. Remedy. The sanctions are sufficient to remedy the problem.

C. Informal Hearings. The violations committee may conduct an informal non-adversarial hearing with the respondent properly noticed of the inquiry regarding the issues to be discussed. The committee shall receive information and deliberate as to a cause of action regarding a potential violation. The committee may recommend a course of action to the full board or dismiss the allegations by an affirmative majority vote of the committee. Should the violations committee recommend a course of action to the full board, the following shall apply.

1. Disclosure. Respondent's testimony or the work product from the informal hearing of any staff or committee member may not be introduced at any subsequent formal hearing.

2. Recusal. Violations committee members shall not be permitted to participate in subsequent formal board hearings pertaining to complaints or alleged violations heard by the violations committee, unless respondent allows otherwise.

D. Interlocutory Hearings. By interlocutory (or summary) hearing, the violations committee may summarily suspend a license, permit, certification, and/or registration prior to a formal administrative board hearing wherein, based upon the committee's judgment and reflected by adequate evidence and an affirmative majority decision, a person poses a danger to the public's health, safety, and welfare, and the danger requires emergency action.

1. Summons Notice. A summary proceeding summons notice shall be served at least five days before the scheduled hearing to afford the respondent an opportunity to be heard with respect to a potential summary suspension action. The notice shall contain a time, place, nature, and the grounds asserted relative to the alleged conduct warranting summary suspension.

2. Burden of Proof. Legal counsel shall have the burden of proof to support the contention that the public's health, safety, or welfare is in danger and requires summary or emergency action.

3. Evidence. The respondent shall have the right to appear personally and/or be represented by counsel to submit affidavits, documentary evidence, or testimony in response to the cause of action asserted as the basis for the summary suspension.

4. Decision. The committee shall determine whether to grant or deny the summary suspension based upon adequate evidence with an affirmative majority vote substantiated by finding(s) of fact and conclusion(s) of law that the public's health, safety, or welfare is in danger and requires emergency or summary action.

5. Report. The committee shall submit their findings and interlocutory decree to the board when rendered.

6. Suspensive Duration. The summary suspension decree shall be followed by a formal administrative hearing within 30 days from receipt of notice by the respondent.

E. Probation Violation Hearings. Probation violation proceedings shall be initiated upon receipt of information indicating that a respondent is in violation of any of the terms or conditions of his probation.

1. Review. Board-designated staff shall receive and review the compliance officer's report and then determine whether a probation violation proceeding is warranted. Should a probation violation hearing be determined warranted, the violations committee shall proceed by interlocutory hearing or informal hearing as deemed appropriate.

2. Notice. Notice shall be afforded the respondent of the allegation(s) forming the basis of the alleged violation status, and the time and place of the appropriate hearing to be conducted.

3. Disposition. Disposition of the hearing shall be according to the appropriate procedures to informal hearings or interlocutory hearings.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

§327. Impairment Committee

A. Impairment. Impairment means a condition that causes an infringement on the ability of an individual to practice, or assist in the practice of, pharmacy sufficient to pose a danger to the public. Impairment may be caused by, but is not limited to, alcoholism, substance abuse or addiction, mental illness, or physical illness.

B. The impairment committee shall have the following responsibilities:

1. supervise the Practitioner Recovery Program;

2. recommend for board consideration any addictionists or other professionals utilized by the program;

3. recommend for board consideration any action for reinstatement of recovering persons;

4. any other related responsibilities deemed appropriate by the board.

C. Practitioner Recovery Program. The board may establish and maintain a recovery program to assist impaired persons through the recovery process so that they may safely return to practice. The board may utilize the services of outside agencies to assist in the recovery of the impaired person.

D. Informal Hearing

1. The board may convene an informal administrative hearing to identify an impaired person and to take appropriate action. The board may require the appearance of any persons deemed necessary to properly conduct an informal hearing. This process shall be conducted by the impairment committee chairman or any other member(s) of the board or staff as the president deems necessary.

2. Any knowledge acquired by any board member or staff in identifying and assisting an allegedly impaired person shall not automatically be grounds for recusal at any later hearing on that same matter.

3. An impaired or allegedly impaired person may enter into a preliminary consent agreement that shall include a mandatory surrender of that person's license, permit, certification, or registration, which shall be delivered to the board office and shall effectively prohibit that person from practicing, or assisting in the practice of, pharmacy. Such person shall agree to enter into an approved treatment and monitoring program as determined by the board. This consent agreement shall not restrain the board from conducting violations proceedings in the matter as it deems necessary.

4. The impairment committee may make recommendations to the full board and/or the violations committee as it deems appropriate on an impaired or allegedly impaired person.

E. Impaired Reinstatement. An application for reinstatement of an impaired person shall be filed with the impairment committee for consideration and recommendation to the violations committee and/or the full board.

1. An impaired person may petition the board for reinstatement of his license, permit, certification, or registration, provided he has:

a. documented proof from an attending physician that he has successfully completed an alcohol or substance abuse recovery program; and

b. a current post-treatment evaluation from a board-approved addictionist; and

c. successfully completed any requirements the board deems necessary with respect to the particular type of impairment;

d. the impairment committee may waive the above requirements for impairments not related to alcohol or substance abuse.

2. After the above stipulations have been met, the person applying for reinstatement may be scheduled for an interview with the impairment committee for consideration of any recommendation to the reinstatement committee and/or the full board.

3. Upon reinstatement, the board may place the reinstated person on probation for a specified length of time and may assign conditions of the probation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2079 (October 2003), effective January 1, 2004.

§329. Formal Hearing

A. Authority. The board shall provide a formal administrative hearing pertaining to the proprietary rights or privilege to practice pharmacy, or operate a pharmacy, or hold a certificate or registration, in accordance with the Administrative Procedure Act, R.S. 49:950 et seq., with authority to take disciplinary action pursuant to R.S. 37:1241 of the Pharmacy Practice Act.

B. Ex-Parte Communication. Once a formal hearing has been initiated and notice served, board members participating in the decision process shall not communicate with a respondent or a respondent's attorney concerning any issue of fact or law involved in the formal hearing.

C. Notice. A formal disciplinary public proceeding may be initiated upon proper notice to a respondent and held at a designated time and place based upon the following grounds:

1. violation—sufficient evidence or a serious complaint of an alleged violation to require a formal hearing shall be directed to legal or special counsel for administrative prosecution to justify a formal hearing; or

2. failure to respond—a failure by the respondent to respond to the violations committee informal inquiry; or

3. irresolvable issues—a violations committee informal hearing fails to resolve all issues and requires further formal action; or

4. irreconcilable issues—an interlocutory hearing fails to resolve all pertinent pending issues thus requiring further formal action; or

5. reaffirmation—reaffirmation of an interlocutory decree; or

6. requirement—a formal administrative hearing requirement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2080 (October 2003), effective January 1, 2004.

§331. Formal Hearing Procedures

A. Hearing Officers

1. Administrative Hearing Officer. The presiding hearing officer may be the board president, a vice-president, or other individual appointed by the president or his successor. The hearing officer has the responsibility to conduct a fair and impartial proceeding with the administrative duty and authority to:

a. convene an administrative board hearing;

b. rule on motions and procedural questions arising during the hearing such as objections or admissibility of evidence or examination of witnesses;

c. issue or direct staff to issue subpoenas;

d. declare recess;

e. maintain order;

f. enforce a standard of conduct to insure a fair and orderly hearing;

g. remove disruptive person(s) from a hearing.

2. Oaths. The presiding hearing officer, executive director, or other board designee may administer oaths.

B. Administrative Jury. The board, comprised of a quorum of members, shall serve as an administrative jury to hear and determine the disposition of the pending matter based on the finding(s) of fact and conclusion(s) of law by receiving evidence and reaching a decision and/or ordering sanctions with an affirmative majority record vote of board members participating in the decision process.

C. Administrative Hearing Clerk. The board's executive director shall serve as the administrative hearing clerk and shall maintain administrative hearing records.

D. Administrative Prosecutor. The legal or special counsel shall prosecute the pending matter and bear the burden of proof to be presented to the board.

E. Administrative Reporting. The board-designated stenographer shall record all testimony dictated and evidence received at the hearing. The utilization of recording equipment may be employed.

F. Hearing Order

1. Docket. Contested matters shall be identified by reference docket number and caption title. The administrative hearing clerk or other staff or board member designated by the presiding hearing officer shall announce the docket and identify persons present or absent in the hearing chambers.

2. Complaint. The complaint may be read at an open hearing unless waived by the respondent.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2080 (October 2003), effective January 1, 2004.

§333. Pre-Hearing Conference

A. Respondents and/or their legal counsel in matters pending before the board may be directed by the presiding administrative hearing officer to appear at a pre-hearing conference to consider the simplification of the issues, admission of facts, or stipulations to documents which may avoid unnecessary proof and such other items as may aid in the disposition of the matter(s) pending.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§335. Consent Agreements

A. Respondents may enter into consent agreements with the board on any matter pending before the board. A consent agreement is not final until the board approves the consent agreement by majority vote of the administrative jury. If the consent agreement is rejected in full or part, the matter shall be heard at the next regularly scheduled board hearing. However, nothing herein shall limit the board from modifying a consent agreement, with respondent's approval, to include less severe sanctions than those originally agreed to in a pending consent agreement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§337. Opening Statement

A. An opening statement by legal or special counsel may present a brief position comment with an outline of evidence to be offered. Respondent or respondent's legal counsel may present an opening defense position statement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§339. Evidence

A. Testimony Received. Testimony shall be received under oath administered by the presiding hearing officer, the executive director, or other staff or board member designated by the hearing officer.

B. Evidence Introduction. All parties shall be afforded an opportunity to present evidence on all issues of fact and argue on all issues of law and respond by direct testimony, followed with cross examination as may be required for a full and true disclosure of the facts. The direct presentation of evidence shall be introduced by the legal or special counsel and shall be followed by the respondent in proper person or by legal counsel by direct and/or cross-examination and/or rebuttal.

C. Examination. Witnesses may be directly examined and cross-examined. Additionally, witnesses and/or respondents may be questioned during an administrative hearing by members of the administrative jury on matters for clarification.

D. Rule Interpretation. Liberal rules of evidence shall be employed by the presiding hearing officer to provide adequate facts and law necessary for the board to deliberate and decide each case. The board's administrative hearing shall not be bound to strict rules of evidence.

E. Admissibility. Admissibility of evidence and testimony shall be determined by the presiding hearing officer as provided by law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§341. Closing Arguments

A. Closing arguments may be made by respondent in proper person or by legal counsel followed by closing arguments from prosecuting legal or special counsel.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§343. Board Decisions

A. The board's decision shall be based on finding(s) of fact and conclusion(s) of law. The board's decision shall be based on clear and convincing evidence presented at a formal hearing, together with the board's determination of any appropriate sanctions, by an affirmative majority record vote of the board members participating in the decision process. Decisions shall be recorded and made part of the record.

1. Board Order. The board's order shall be rendered at the open hearing or taken under advisement and rendered within 30 days of the hearing and then served personally or domiciliary at the respondent's last known address by regular, registered, or certified mail, or by a diligent attempt thereof.

2. Finality of Board Order. The board's order becomes final eleven days after receipt of notification of the board's decision by respondent, provided an appeal is not filed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§345. Complaint Dismissal

A. The board, in their discretion and based upon lack of evidence, may orally dismiss at an open hearing a pending matter or parts thereof.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§347. Transcripts

A. A complete record of all formal hearing proceedings shall be transcribed, maintained, and available upon written request with sufficient costs of the preparation of the transcript for a minimum of three years from the date the pertinent order(s) is final.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§349. Contempt

A. A failure of a respondent or witness to comply with a board order, after being duly served, constitutes contempt and the board may petition a court of competent jurisdiction to rule the witness or respondent in court to show cause why he should not be held in contempt of court.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§351. Administrative Review

A. Rehearing. An aggrieved respondent may file within 10 days a rehearing motion in proper form requesting reconsideration or a rehearing by the board or by the interlocutory hearing panel.

B. Grounds. The board or an interlocutory hearing panel may reconsider the motion for rehearing at the next regularly scheduled board meeting. The grounds for such action shall be either that:

1. the board's decision was clearly contrary to the law or evidence; or

2. newly discovered evidence not available at the time of the hearing which may be sufficient to reverse the board's decision; or

3. issues not previously considered ought to be examined; or

4. it is in the public interest to reconsider the issues and the evidence.

C. Time. The board or an interlocutory hearing panel shall grant or deny the petition for rehearing within 30 days after its submission.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004.

§353. Judicial Review

A. An aggrieved respondent may appeal the board's decision to a court of appropriate jurisdiction within 30 days from the board order or rehearing motion denial.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1248.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004.

§355. Reporting

A. The board may publish in the board's newsletter the sanctions imposed by the board that are of public interest and the public's right to know.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004.

§357. Reinstatement

A. An application for reinstatement based on revocation or suspension of a pharmacist license, pharmacy permit, certification, registration, or any other designation authorized by the board shall be filed with and heard by the reinstatement committee for consideration and recommendation to the full board. The board may then hold a formal hearing whereby the burden of proof shifts to the applicant to demonstrate and support with substantial evidence respondent's rehabilitation and that the reinstatement of the license, permit, certification, registration, or other board-authorized designation at issue would not pose a danger to the public's health, safety, or welfare.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004.

§359. Declaratory Statements and Advisory Opinions

A. The board may issue declaratory rulings in accordance with the Administrative Procedure Act, R.S. 49:950 et seq. These may include a declaratory statement or an advisory opinion, in the form of a ruling which has the same status as board decision in adjudicated cases, in response to a request for clarification of the effect of rules and regulations or of R.S. 37:1161 et seq. Advisory opinions as a statement of the board's ruling are generally rendered in cases that relate to specific situations. Declaratory statements contain the board's ruling relative to the petition, with the principles and rationale that support the ruling. Declaratory statements are generally rendered in situations that relate to widespread situations. Neither an advisory opinion nor a declaratory statement has the binding force of law, but they represent the board's expert opinion relative to the matter in question.

B. A request for a declaratory statement or for an advisory opinion is made in the form of a petition to the board. At a minimum, the petition shall include:

1. the name and address of the petitioner;

2. specific reference to the statutes or rules and regulations to which the petition relates;

3. a concise statement of the manner in which the petitioner is aggrieved by the rule, regulation, or statute, or by its potential application to the petitioner, or in which the petitioner is uncertain of its effects;

4. a statement of whether an oral hearing is desired; and

5. other information appropriate for the board's deliberation on the request.

C. Said petition shall be considered by the board at its next regularly scheduled meeting provided that the petition has been filed at least 60 days prior to the next scheduled board meeting.

D. The declaratory statement/advisory opinion of the board on said petition shall be in writing and mailed to petitioner at the last address furnished to the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004.

Chapter 5. Pharmacists

Subchapter A. Licensure Procedures

§501. Application

A. An application for initial pharmacist licensure, whether by examination or reciprocity, shall be submitted, with appropriate fee, to the board at least 30 days prior to any examination. An application shall expire one year after the date of receipt in the board office.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004.

§503. Examination

A. Examination. A board-approved licensure examination shall consist of integrated pharmacy subject matters and any other disciplines the board may deem appropriate in order to demonstrate competence. An applicant shall achieve a passing score, as determined by the board, in the pharmacy examination.

B. Re-Examination

1. Following the first or second unsuccessful attempt of an examination for licensure, an applicant may be permitted to attempt that examination for licensure.

2. Following the third unsuccessful attempt of an examination for licensure, an applicant shall not be permitted to attempt that examination for licensure until one year from the date of the last examination.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2083 (October 2003), effective January 1, 2004.

§505. Licensure

A. The board shall issue a license upon payment of appropriate fees when the board is satisfied the applicant is competent to practice pharmacy in the state.

1. License Display. A pharmacist's license shall be displayed in a conspicuous place in the principal location where the pharmacist is engaged in the practice of pharmacy and in such a manner that said license may be seen by patrons.

2. Identification Card. The board shall issue an identification card to a pharmacist who completes the licensure process. A pharmacist shall have this identification card on his person when practicing outside of his principal practice site in order to show proof of licensure.

3. Renewal. The board shall mail the annual pharmacist license renewal application to all currently licensed Louisiana pharmacists prior to November 1. The completed application along with the appropriate fee shall be submitted to the board by December 31 of each year. A pharmacist's renewal of licensure shall be displayed in the principal location where the pharmacist is engaged in the practice of pharmacy and in such a manner that said renewal may be seen by patrons. A renewal of licensure shall serve as proof of licensure and a pharmacist's license to practice pharmacy for that year of issuance.

a. Active. A pharmacist applicant shall pay the annual renewal fee, attain minimum continuing pharmacy education (CPE) as required, and complete and submit the annual renewal form to the board office before December 31 of each year.

b. Inactive. A pharmacist applicant may make a written request for inactive status from the board. The inactive pharmacist must complete the annual renewal form furnished by the board and submit it with the appropriate fee to the board before December 31 of each year. An inactive pharmacist shall not engage in the practice of pharmacy and is not required to obtain CPE. In order to upgrade an inactive license to active status, an inactive pharmacist shall petition the board and meet requirements of the reinstatement committee and the board. The board shall set the requirements necessary to assure competency for each individual applying for active status.

4. Expired License. A pharmacist license that has not been renewed by December 31 of each year shall expire and be null and void. The holder of an expired license may submit a written request, complete with any supporting documentation, for reinstatement to the board. The request may be referred preliminarily to the board's reinstatement committee for an informal hearing and recommendation that may be considered by the board at its next regularly scheduled meeting. The board may reinstate an expired license upon payment of applicable annual, delinquent, and lapsed license fees pursuant to R.S. 37:1184, as amended, and other conditions as the board deems appropriate.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2083 (October 2003), effective January 1, 2004.

§507. Continuing Education Program

A. The board, recognizing that professional competency is a safeguard for the health, safety, and welfare of the public, shall require continuing pharmacy education as a prerequisite for annual licensure renewal for pharmacists.

B. Definitions

1. *ACPE*—American Council on Pharmaceutical Education.

2. *CPE*—continuing pharmacy education, a structured postgraduate educational program for pharmacists to enhance professional competence.

3. *CPE Unit*—a standard of measurement adopted by the ACPE for the purpose of accreditation of CPE programs. One CPE unit is equivalent to 10 credit hours.

C. Requirements

1. A minimum of one and one-half ACPE or board-approved CPE units, or 15 hours, shall be required each year as a prerequisite for pharmacist licensure renewal.

2. Pharmacists shall maintain copies of individual records of personal CPE activities at their primary practice site for two years and present them when requested by the board.

3. When deemed appropriate and necessary by the board, some or all of the required number of hours may be mandated on specific subjects. When so deemed, the board shall notify all licensed pharmacists prior to the beginning of the year in which the CPE is required.

D. Compliance

1. Complete compliance with CPE rules is a prerequisite for pharmacist licensure renewal.

2. Non-compliance with the CPE requirements shall be considered a violation of R.S. 37:1241(A)(2), and shall constitute a basis for the board to refuse licensure renewal.

3. The failure to maintain an individual record of personal CPE activities, or falsification of CPE documents, shall be considered a violation of R.S. 37:1241(A)(22).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1306 (October 1997), LR 29:2083 (October 2003), effective January 1, 2004.

§509. Address Change

A. A licensed pharmacist shall notify the board within 10 days, with documentation, attesting to any change of mailing and/or home address. This documented notice shall include the pharmacist's full name and license number, and the old and new address.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2083 (October 2003), effective January 1, 2004.

§511. Employment Change

A. A licensed pharmacist shall notify the board within 10 days, with documentation, attesting to any change in employment. This documented notice shall include the pharmacist's full name and license number, the name and address of old and new employment, and the permit numbers of those pharmacies involved.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2084 (October 2003), effective January 1, 2004.

§513. Certified Pharmacist Preceptor Program

A. Qualifications for Certified Pharmacist Preceptor Applicants

1. The applicant shall be currently licensed and shall have been actively practicing for not less than two consecutive years prior to the date of application.

2. The applicant shall not be on probation with the board at the time of application.

B. Certified Pharmacist Preceptor Requirements

1. The applicant shall complete a board-approved certified pharmacy preceptor training program.

2. The applicant shall complete an Application for Pharmacist Preceptor Certification. The board may issue a Pharmacist Preceptor Certification after verification that all requirements have been satisfied.

a. The Pharmacist Preceptor Certificate shall expire five years after the date of issue, and may be renewed upon application to the board and verification by the board that all requirements have been satisfied.

b. The board shall reserve the right to refuse to issue or terminate any Pharmacist Preceptor Certification for cause.

c. The Pharmacist Preceptor Certification shall be conspicuously displayed at the primary preceptor pharmacy location.

C. A Certified Pharmacist Preceptor Program shall meet all requirements established by the board.

D. A certified pharmacist preceptor shall not supervise more than one intern at any given time. Interns satisfactorily progressing in their final academic year in a board-approved college of pharmacy shall not be counted in that 1:1 ratio.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2084 (October 2003), effective January 1, 2004.

Subchapter B. Professional Practice Procedures

§515. Prospective Drug Utilization Review

A. A pharmacist shall review the patient record and each prescription presented for dispensing for purposes of enhancing pharmacy care and therapeutic outcomes by recognizing the following potential situations:

1. drug over-utilization or under-utilization;

2. therapeutic duplication;

3. drug-disease contraindications;

4. drug-drug interactions;

5. inappropriate drug dosage or treatment duration;

6. drug-allergy interactions; or

7. clinical abuse/misuse.

B. Upon recognizing any of the above situations, the pharmacist, using professional judgment, shall take appropriate actions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2084 (October 2003), effective January 1, 2004.

§517. Patient Counseling

A. Patient counseling means the effective communication by a pharmacist of information to the patient or caregiver, in order to ensure proper use of drugs and devices.

B. Minimum Requirements. At a minimum, the pharmacist should be convinced that the patient or caregiver is informed of the following:

1. name and description of the medication;

2. dosage form, dosage, route of administration, and duration of therapy;

3. special directions and precautions for preparation, administration, and use by the patient;

4. common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required in the event of their occurrence;

5. techniques for self-monitoring drug therapy;

6. proper storage of the medication;

7. prescription refill information, if any; and

8. the action to be taken in the event of a missed dose.

C. The pharmacist may supplement oral information with written information, but shall not use written information alone to fulfill the counseling requirement.

D. Patient Information

1. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

a. name, address, and telephone number;

b. date of birth (or age) and gender;

c. allergies/drug reactions, disease state(s); and

d. current list of all medications.

E. Communication to the Patient

1. A pharmacist shall counsel the patient or caregiver "face-to-face" when possible or appropriate. If it is not possible or appropriate to counsel the patient or caregiver "face-to-face," then a pharmacist should counsel the patient or caregiver by using alternative methods. The pharmacist shall exercise his professional judgment in the selection of alternative methods, including but not limited to, telephonic or electronic communication with the patient or caregiver.

2. A pharmacist shall provide patient counseling to patients discharged from hospitals and/or other institutions, where applicable. However, counseling shall not be required for inpatients of a hospital or institution where a nurse or other licensed health care professional is authorized to administer medication(s).

3. The pharmacist shall maintain appropriate patient-oriented drug information materials for use by the patient upon request.

F. Waiver. No pharmacist or pharmacy may solicit or encourage blanket waivers for patient counseling. However, nothing in this regulation shall prohibit the patient or caregiver from declining patient counseling.

AUHTORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2084 (October 2003), effective January 1, 2004.

§519. State of Emergency

A. When the governor issues, or renews, a state of emergency pursuant to the Emergency Assistance and Disaster Act of 1993, R.S. 29:721 et seq.:

1. a pharmacist may work in the affected parish(es) and may dispense a one-time emergency prescription of up to a 30 day supply of a prescribed medication if:

a. in the pharmacist's professional opinion the medication is essential to the maintenance of life or to the continuation of therapy; and

b. the pharmacist makes a good faith effort to reduce the information to a written prescription marked "Emergency Prescription," then file and maintain the prescription as required by law;

2. a pharmacist not licensed in Louisiana, but currently licensed in another state, may dispense prescription medications in those affected parish(es) during the time that a state of emergency exists if:

a. the pharmacist has some type of identification to verify current licensure in another state; and

b. the pharmacist is engaged in a legitimate relief effort during the emergency period.

B. The authority provided for in this Section shall cease with the termination of the state of emergency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2085 (October 2003), effective January 1, 2004.

§521. Prescription Orders to Administer Medications

A. Purpose. The rules of this Section describe the minimum requirements for the administration of medications to patients by Louisiana-licensed pharmacists.

B. A licensed pharmacist may administer medication directly to a patient upon the prescription or order of a practitioner. Such a prescription or order shall be known as an "authority to administer."

1. An authority to administer is valid only for the pharmacist meeting the requirements herein and is not transferable.

2. An authority to administer, once granted, is valid for a period of time not to exceed six months, unless revoked sooner by the practitioner granting the order.

C. A properly executed authority to administer shall:

1. identify the licensed practitioner's name, office address, and telephone number;

2. bear the patient's name, address, gender, and date of birth;

3. identify the medication, dose, and route of administration;

4. identify the pharmacist authorized to administer the medication; and

5. bear the date of the original order and the date of any authorized subsequent dose administrations.

D. Requirements. Unless otherwise specifically authorized by the board, a pharmacist shall meet the following minimum standards to qualify for an authority to administer:

1. obtain and maintain a license to practice pharmacy from the board;

2. successfully complete a board-approved course of study from a board-approved provider that:

a. requires documentation by the pharmacist of current certification in the American Heart Association's Basic Cardiac Life Support for Healthcare Providers, its successor, or board-approved equivalent;

b. is an evidence-based didactic course that meets current Centers for Disease Control and Prevention (CDC) training guidelines, or other guidelines as designated by the board, and provides a minimum of 20 hours of instruction and experiential training in the following content areas:

i. standards for medication administration practices;

ii. basic immunology;

iii. recommended medication administration schedules;

iv. vaccine storage and management;

v. informed consent;

vi. physiology and techniques for medication administration;

vii. pre- and post-administration assessment and counseling;

viii. medication administration record management; and

ix. management of adverse events, including identification and appropriate response, as well as documentation and reporting; and

c. provides documentation of the successful completion of the course to the participant.

i. The pharmacist shall display the certificate of completion in the primary practice site.

ii. The pharmacist shall submit a copy of said certificate to the board office for placement in the pharmacist's permanent file.

E. The pharmacist shall maintain continuing competency to accept an Authority to Administer, as evidenced by:

1. a current certification by the American Heart Association's Basic Cardiac Life Support for Healthcare Providers, its successor, or board-approved equivalent; and

2. successful completion of at least one hour of continuing education per year related to this area of practice.

F. Vaccines. The pharmacist shall maintain and furnish the following information to the practitioner within 24 hours of the administration:

1. name and address of the patient;

2. age of the patient, if under 14 years of age;

3. name of the patient's primary care physician as provided by the patient or patient's agent;

4. name, manufacturer, and lot number of the vaccine administered;

5. amount administered;

6. date of vaccine administration;

7. site of vaccine administration;

8. route of administration; and

9. name, address, and telephone number of the pharmacist administering the vaccine.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2085 (October 2003), effective January 1, 2004.

Chapter 7. Pharmacy Interns

§701. Definition

A. A *pharmacy intern* is an individual who is not yet licensed as a pharmacist in any jurisdiction, and is:

1. engaged in the practice of pharmacy while under the direct and immediate supervision of a pharmacist for the purpose of obtaining practical experience for licensure as a pharmacist, and is satisfactorily progressing in a board-approved college of pharmacy; or

2. a graduate of a board-approved college of pharmacy awaiting examination for licensure; or

3. a graduate who has established educational equivalency through a program approved by the board; or

4. an individual participating in a residency or fellowship.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2086 (October 2003), effective January 1, 2004.

§703. Registration

A. All pharmacy interns shall meet the following requirements for registration.

1. All pharmacy interns shall register with the board. The failure to register may result in disciplinary action by the board.

a. The applicant shall submit to the board office a properly completed application no later than the end of the first semester of the first academic year at a board- approved college of pharmacy.

b. The board may issue an intern registration to the applicant, upon receipt of a properly completed application, appropriate fee, and any other documentation required by the board office.

c. The intern registration shall expire one year after the certification of graduation from a board-approved college of pharmacy.

d. The intern registration shall be conspicuously displayed at the preceptor site.

e. The board shall reserve the right to recall or refuse to issue any intern registration for cause.

2. A pharmacy intern shall wear appropriate attire and be properly identified with his name and intern status while on duty at the preceptor site.

3. A pharmacy intern shall notify the board in writing within 10 days of a change of address. This notice shall include the pharmacy intern's name, registration number, and old and new addresses.

4. A pharmacy intern shall notify the board in writing within 10 days of a change in location(s) of employment. This notice shall include the pharmacy intern's name and registration number, the name and address of old and new employment, and the permit numbers of those pharmacies involved.

5. The pharmacy intern shall be non-impaired.

a. The pharmacy intern is subject to confidential random drug screen testing and/or evaluations.

b. A positive drug screen may be self evident as proof of improper drug use. For the purposes of this Chapter, a missed screen, a screen submitted beyond the mandated period, and/or any screen submitted indicating the sample provided is diluted, substituted, or in any way adulterated is considered to be a positive drug screen.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2086 (October 2003), effective January 1, 2004.

§705. Practical Experience

A. All applicants for licensure by examination shall earn practical experience in the practice of pharmacy concurrent with attending or after graduation from a board-approved college of pharmacy.

B. The practical experience shall be predominantly related to the provision of pharmacy primary care and the dispensing of drugs and medical supplies, the compounding of prescriptions, and the keeping of records and making of reports as required under federal and state law.

1. The practical experience earned shall have been under the supervision of a certified pharmacist preceptor.

2. A pharmacy intern shall not earn hours in a permitted pharmacy site that is on probation with the board or under the supervision of a pharmacist who is on probation with the board.

C. Practical Experience Hours. Interns shall supply, on an affidavit form supplied by the board office, evidence of earning at least 1,500 hours of practical experience. Interns may submit their affidavit(s) to the board office for credit approval either prior to, or concurrent with, their application for pharmacist licensure.

1. In order to receive credit for the 1,500 hours of practical experience upon certification of graduation, a pharmacy intern shall comply with the following:

a. prior to beginning his final academic year in a board-approved college of pharmacy, the intern shall earn a minimum credit of 500 hours under the supervision of a certified pharmacist preceptor at a permitted pharmacy site; and

b. The intern shall earn a minimum credit of 1,000 hours within the board-approved college of pharmacy's professional experience curriculum; and further, of the 1,000 hours within that professional experience curriculum, not less than 300 hours shall be earned in a traditional community pharmacy dispensing practice, and not less than 300 hours shall be earned in a traditional hospital pharmacy dispensing practice, as certified by the dean of the college of pharmacy.

2. If credit is not received for the total required 1,500 hours upon certification of graduation pursuant to the provisions of §705.C.1, the intern shall earn 1,500 hours of practical experience under the supervision of a certified pharmacist preceptor at a permitted pharmacy site after certification of graduation from a board-approved college of pharmacy.

3. Practical experience hours earned either prior to the final academic year, or after certification of graduation from a board-approved college of pharmacy, that are submitted to the board for credit consideration shall be listed on an affidavit form supplied by the board office, and signed by the certified pharmacist preceptor and pharmacy intern.

a. A pharmacy intern may receive credit for a maximum of 50 hours per week.

b. A separate affidavit shall be required from each permitted pharmacy site.

c. No credit shall be awarded for hours earned within the professional experience curriculum of a board-approved college of pharmacy, nor for hours earned outside the professional experience curriculum but at the same time and location as hours earned for that professional experience curriculum.

4. Certification of Hours to and from Another Jurisdiction.

a. Interns enrolled in a board-approved college of pharmacy in Louisiana who earn hours of practical experience in another jurisdiction, as well as interns enrolled in a board-approved college of pharmacy in another jurisdiction who earn hours of practical experience in another jurisdiction, may transfer those hours to Louisiana under the following conditions:

i. the hours of practical experience shall be listed on an affidavit form supplied by the Louisiana Board of Pharmacy, signed by the preceptor pharmacist and the intern, and submitted to the Louisiana Board of Pharmacy for consideration of credit; and

ii. the board of pharmacy in the jurisdiction where the hours were earned shall certify those hours to the Louisiana Board of Pharmacy;

iii. the Louisiana Board of Pharmacy may grant credit for all hours that comply with the Louisiana Board of Pharmacy's requirements as delineated in this Section.

b. Upon written request by the pharmacy intern, the Louisiana Board of Pharmacy may certify practical experience hours earned in Louisiana to a board of pharmacy in another jurisdiction.

5. Credited hours of practical experience shall expire on the expiration date of the intern registration.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2086 (October 2003), effective January 1, 2004.

Chapter 9. Pharmacy Technicians

§901. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section:

ACPE—Accreditation Council for Pharmacy Education.

CPE—continuing pharmaceutical education, as part of a postgraduate educational program to enhance professional competence.

CPE unit—a standard of measurement adopted by the ACPE for the purpose of accreditation of CPE programs. One CPE unit is equivalent to 10 credit hours.

Pharmacist Preceptor—an individual who is currently licensed as a pharmacist by the board, meets certain qualifications as established by the board, and is responsible for the instructional training of pharmacy technician candidates.

Pharmacy Technician—an individual, certified by the board, who assists in the practice of pharmacy under the direct and immediate supervision of a Louisiana-licensed pharmacist.

Pharmacy Technician Candidate—an individual not yet certified as a pharmacy technician by the board who is:

a. an individual who possesses a valid registration, is satisfactorily progressing in a board-approved structured program, and is working under the supervision of a pharmacist preceptor for the purpose of obtaining practical experience for certification as a pharmacy technician by the board; or

b. an individual who possesses a valid registration, has successfully completed a board-approved structured program, and is awaiting examination.

Structured Program—systematic instruction in pharmacy related functions in a board-approved pharmacy technician training program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2485 (November 2004), effective January 1, 2005.

§903. Pharmacy Technician Candidates

A. Registration

1. Qualifications

a. All pharmacy technician candidates shall register with the board; failure to do so may result in disciplinary action by the board.

b. The candidate shall be at least 18 years of age, as evidenced by a valid and legible copy of a birth certificate or other appropriate credential.

c. The candidate shall be of good moral character and non-impaired.

d. The candidate shall be a graduate from a high school approved by a state department of education, or shall possess an equivalent degree of education, as evidenced by a valid and legible copy of a diploma, transcript, or other appropriate credential.

e. Exceptions

i. A pharmacist or pharmacist intern whose board credential has been denied, suspended, revoked, or restricted for disciplinary reasons by any board of pharmacy shall not be a pharmacy technician candidate or pharmacy technician.

ii. A pharmacist or pharmacist intern whose board credential is lapsed shall not be a pharmacy technician candidate or pharmacy technician until such lapsed credential is recalled through non-disciplinary board action.

2. Issuance and Maintenance

a. Upon receipt of a properly completed application, appropriate fee, proof of enrollment in a board-approved structured program, and any other documentation required by the board, the board may issue a pharmacy technician candidate registration to the applicant.

b. The board reserves the right to refuse to issue, recall, or discipline a registration for cause.

c. The registration shall expire 18 months after the date of issuance, and it shall not be renewable.

d. A pharmacy technician candidate shall notify the board, in writing, no later than 10 days following a change of mailing address. The written notice shall include the candidate's name, registration number, and old and new addresses.

e. A pharmacy technician candidate shall notify the board, in writing, no later than 10 days following a change in either training program site or location(s) of employment. The written notice shall include the candidate's name, registration number, and name, address, and permit numbers for old and new training program sites or employers.

B. Structured Program

1. All structured programs shall meet competency standards as established by the board.

2. The curriculum of the structured program shall be composed of the elements contained in the *Pharmacy Technician Training Program Minimum Competencies*, as approved by the board.

3. The structured program shall notify the board when a pharmacy technician candidate is no longer satisfactorily progressing in the program.

4. The structured program shall provide an appropriate credential to the candidate who has successfully completed the program.

C. Practical Experience

1. The candidate shall possess a registration prior to earning any practical experience in a pharmacy.

2. The candidate's registration shall be conspicuously displayed in the prescription department.

3. The candidate shall wear appropriate attire and be properly identified as to name and candidate status while on duty in the prescription department.

4. A candidate shall not work in a permitted site that is on probation with the board, or with a pharmacist who is on probation with the board.

5. The candidate's registration shall evidence his authority to earn a minimum of 600 hours of practical experience in a pharmacy, under the supervision of a pharmacist preceptor, in satisfaction of the requirements for pharmacy technician certification. Of the required minimum 600 hours, not less than 200 hours shall be earned during and as part of a structured program.

6. A candidate may receive board credit for a maximum of 50 hours per week.

7. Hours of practical experience earned by a candidate shall expire one year after the expiration date of the registration.

D. Examination

1. A board-approved technician examination shall consist of integrated pharmacy subject matter and any other disciplines the board may deem appropriate in order to permit the candidate to demonstrate his competency. The candidate shall achieve a passing score, as determined by the board.

2. Re-Examination

a. Following the first or second unsuccessful attempt of an examination, the candidate may be permitted to retake that examination.

b. Following the third unsuccessful attempt of an examination, the candidate shall wait one year after the date of the last examination to retake that examination. If the candidate fails to wait the prescribed one year period, the board may delay any future certification until that one year period has elapsed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2485 (November 2004), effective January 1, 2005.

§905. Pharmacy Technician Certificate

A. Qualifications

1. An applicant for a pharmacy technician certificate shall be at least 18 years of age, as evidenced by a valid and legible copy of a birth certificate or other appropriate credential.

2. An applicant shall be of good moral character and non-impaired.

3. An applicant shall demonstrate the following educational competencies:

a. shall be a graduate from a high school approved by a state department of education, or shall possess an equivalent degree of education, as evidenced by a valid and legible copy of a diploma, transcript, or other appropriate credential; and

b. shall have successfully completed a board-approved structured program for pharmacy technician education and training, as evidenced by a valid and legible copy of the appropriate credential from that program.

4. An applicant shall demonstrate evidence of at least 600 hours of practical experience under the supervision of a pharmacist preceptor, using a form supplied by the board.

5. An applicant shall demonstrate successful completion of a board-approved technician examination, as evidenced by a valid and legible copy of the appropriate credential.

B. Issuance and Maintenance

1. Upon receipt of a properly completed and notarized application, properly executed preceptor affidavit(s), copies of valid and legible credentials, and the appropriate fee, and following verification that all requirements have been satisfied, the board may issue a pharmacy technician certificate to the applicant for the current renewal period.

2. The board reserves the right to refuse to issue, recall, or discipline a certificate for cause.

3. The annual renewal shall expire and become null and void on June 30 of each year.

a. The board shall mail, no later than May 1 of each year, an application for renewal to all pharmacy technicians to the address of record.

b. The completed application, along with the appropriate fee, shall be submitted to the board by June 30 of each year.

c. A pharmacy technician shall not assist in the practice of pharmacy in Louisiana with an expired renewal.

d. An application for an expired pharmacy technician renewal, along with the appropriate fee, shall be submitted to the board's reinstatement committee for consideration.

4. A pharmacy technician shall notify the board, in writing, no later than 10 days following a change of mailing address. The written notice shall include the technician's name, certificate number, and old and new addresses.

5. A pharmacy technician shall notify the board, in writing, no later than 10 days following a change in location(s) of employment. The written notice shall include the technician's name, certificate number, and name, address, and permit numbers for old and new employers.

6. Upon written request of any certified pharmacy technician in active military service of the United States or any of its allies, the board may waive the requirement for the annual renewal of the certificate, including fees.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2486 (November 2004), effective January 1, 2005.

§907. Scope of Practice

A. Pharmacy technician candidates and pharmacy technicians may assist the pharmacist by performing those duties and functions assigned by the pharmacist while under his direct and immediate supervision.

1. The ratio of candidates to pharmacists on duty shall not exceed one to one at any given time.

2. The ratio of technicians to pharmacists on duty shall not exceed two to one at any given time.

B. Pharmacy technician candidates and pharmacy technicians shall not:

1. receive verbal initial prescription orders;

2. give or receive verbal transfers of prescription orders;

3. interpret prescription orders;

4. compound high-risk sterile preparations, as defined by the United States Pharmacopeia (USP), or its successor;

5. counsel patients.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2486 (November 2004), effective January 1, 2005.

§909. Continuing Education

A. A minimum of one ACPE or board-approved CPE unit, or 10 credit hours, shall be required each year as a prerequisite for annual renewal of a pharmacy technician certificate. Such CPE units shall be credited in the 12-month period prior to the expiration date of the certificate.

B. Certified pharmacy technicians shall maintain copies of their individual records of personal CPE activities at their primary practice site for at least two years, and shall present them when requested by the board.

C. If judged appropriate by the board, some or all of the required number of hours may be mandated on specific subjects. When so deemed, the board shall notify all certified pharmacy technicians prior to the beginning of the renewal year in which the CPE is required.

D. Complete compliance with CPE rules is a prerequisite for renewal of a pharmacy technician certificate.

1. Non-compliance with the CPE requirements shall be considered a violation of R.S. 37:1241(A)(2) and shall constitute a basis for the board to refuse annual renewal.

2. The failure to maintain an individual record of personal CPE activities, or falsifying CPE documents, shall be considered a violation of R.S. 37:1241(A)(22).

3. The inability to comply with CPE requirements shall be substantiated by a written explanation, supported with extraordinary circumstances, and submitted to the board for consideration.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2487 (November 2004), effective January 1, 2005.

§911. Impairment

A. Pharmacy technician candidates and pharmacy technicians shall be non-impaired.

B. Pharmacy technician candidates and pharmacy technicians who have knowledge that a pharmacist, pharmacist intern, pharmacy technician candidate, or pharmacy technician is impaired shall notify the board of that fact.

C. Pharmacy technician candidates and pharmacy technicians shall be subject to a medical evaluation for impairment by a board-approved addictionist, as authorized by the Louisiana Pharmacy Practice Act, R.S. 37:1161 et seq.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2487 (November 2004), effective January 1, 2005.

Chapter 11. Pharmacies

Subchapter A. General Requirements

§1101. Pharmacy

A. Qualification. Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

B. Appearance. The applicants, including the pharmacist-in-charge, may be required to personally appear before the board prior to a board decision on the permit application.

C. Pharmacy Permit

1. Initial. A completed pharmacy permit application shall be signed by the pharmacist-in-charge and the owner of the pharmacy and submitted to the board for approval.

2. Renewal. A pharmacy permit that has not been renewed by December 31 of each year shall expire and be null and void.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2087 (October 2003), effective January 1, 2004.

§1103. Prescription Department Requirements

A. A prescription department of a pharmacy shall provide sufficient floor space allocated to ensure that drugs are compounded and dispensed in a well lighted, ventilated, climate controlled, and safely enclosed structure.

B. Restricted. A prescription department is a restricted area.

C. Square Footage. A prescription department that is new or remodeled on or after January 1, 2004 shall be not less than 300 total square feet, and shall be inaccessible to the public.

D. Prescription Counter. A prescription counter on which to compound or dispense medications shall have a working surface of not less than a minimum of 24 total square feet. The minimum unobstructed free working surface shall be kept clear at all times for the compounding or dispensing of prescriptions.

E. Prescription Aisle Space. The aisle space behind the prescription counter shall be not less than 30 inches in width.

F. Prescription Department Plumbing. A sink equipped with hot and cold running water shall be located within the prescription department. A sink located in a pharmacy restroom shall not be sufficient to satisfy this requirement.

G. Electronic Record Keeping System. An electronic record keeping system shall be utilized in a pharmacy department and shall be a complete, accurate, and readily retrievable prescription record keeping and storage system.

H. Drug Inventory

1. Storage. The pharmacy shall provide sufficient space on-site for proper storage of labels, prescription containers, and an adequate prescription inventory in order to compound and dispense prescription orders. Drugs that require special storage shall be properly stored.

2. Missing or Damaged Inventory. When significant drug inventory is missing or damaged for any reason, the pharmacy owner or pharmacist-in-charge shall file with the board a signed statement of the circumstances of such occurrence and evidence that the appropriate law enforcement authorities were notified as required by law.

3. Equipment. The pharmacy shall provide sufficient fixtures, equipment, and utensils to ensure that drugs are properly compounded and dispensed.

I. Pharmacy Security. The prescription department shall be adequately secured by the installation of partitions and secured entrances, which shall be locked by a pharmacist and made inaccessible when the prescription department is closed. Any premises housing a prescription department shall be adequately secured by an alarm system.

J. Emergency Access. An additional key to the prescription department may be maintained in a secure location outside the prescription department for use during an emergency. A log shall be maintained with the key, indicating the name of each non-pharmacist using this key, the date and time of entry, and the nature of the emergency.

K. References. A printed copy of the *Louisiana Board of Pharmacy Laws and Regulations* shall be maintained and readily available within the prescription department of a pharmacy. The pharmacy shall maintain access to current and appropriate reference materials pertinent to the pharmacy practice, including but not limited to, pharmacology, drug interactions, dosing, toxicity, and patient counseling.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2087 (October 2003), effective January 1, 2004.

§1105. Pharmacist-in-Charge

A. An initial and renewal pharmacy permit application shall designate and identify the licensed pharmacist-in-charge.

B. Authority and Accountability. The pharmacist-in-charge shall be ultimately responsible for complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

C. Policy and Procedure Manual. The pharmacist-in-charge shall be responsible for the implementation of policies and procedures regarding quality pharmacy services including drug control, distribution, patient compliance accountability, inspection, and record keeping.

D. Circumvention. It is a violation of the pharmacy permit for any person to subvert the authority of the pharmacist-in-charge by impeding the management of the prescription department in the compliance of federal and state pharmacy laws and regulations.

E. Records. The pharmacist-in-charge shall be responsible for the proper maintenance of all prescription records. This necessarily includes electronic prescription records and the system's compliance and capacity to produce the required records.

F. Recall. The pharmacist-in-charge shall be responsible for the implementation of a recall procedure that can be readily activated to assure patient safety.

G. Discontinued and Outdated Drugs. The pharmacist-in-charge shall be responsible for the implementation of policies and procedures to ensure that discontinued or outdated drugs, or containers with worn, illegible, or missing labels are withdrawn from the pharmacy inventory.

H. Change of Pharmacist-in-Charge. Written notice to the board shall be required when the pharmacist-in-charge designation for a pharmacy has changed.

1. The permit holder shall notify the board within 10 days of the prior pharmacist-in-charge's departure date. The permit holder shall designate a new pharmacist-in-charge within 10 days of the departure of the prior pharmacist-in-charge.

2. The new pharmacist-in-charge shall afford the board written notice of his newly designated pharmacist-in-charge status within 10 days of the departure of the prior pharmacist-in-charge.

3. A pharmacist-in-charge who voluntarily leaves a pharmacy shall give written notice to the board and the owner of the permit at least ten days prior to this voluntary departure, unless replaced in a shorter period of time.

I. Affidavit of Responsibility and Duties. The designated pharmacist-in-charge shall sign an affidavit on a form supplied by the board indicating his understanding and acceptance of the duties and responsibilities of a pharmacist-in-charge. This notarized document shall be submitted to the board for inclusion in the pharmacy's record in the board office.

J. A pharmacist shall not hold a pharmacist-in-charge position at more than one pharmacy permit, unless approved by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2088 (October 2003), effective January 1, 2004.

§1107. Pharmacy Operation

A. A pharmacist shall be on duty at all times during regular open hours of the pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2088 (October 2003), effective January 1, 2004.

§1109. Pharmacist Temporary Absence

A. A pharmacist shall be considered to be temporarily absent from the prescription department when not within the confines of the prescription department but remains on-site.

B. The pharmacist may be temporarily absent from the prescription department for breaks and meal periods without closing the prescription department and removing pharmacy personnel providing the following conditions are met:

1. at least one certified pharmacy technician or pharmacy intern remains in the prescription department;

2. the pharmacist is available for emergencies;

3. the temporary absence does not exceed 30 minutes at a time and a total of 60 minutes in a 12-hour period;

4. the pharmacist reasonably believes that the security of the prescription department will be maintained in his absence; and

5. a notice is posted that includes the following information:

a. the fact that the pharmacist is taking a break; and

b. the time the pharmacist will return.

C. If the pharmacist, in his professional judgment, determines it necessary, all personnel shall be removed from the pharmacy and the pharmacy shall be secured for the duration of the temporary absence, and notice shall be posted indicating the pharmacy is closed.

D. During a temporary absence, certified pharmacy technicians or pharmacy interns may continue to process prescription orders, provided that no orders processed during the pharmacist's temporary absence be removed from the prescription department prior to the final check by the pharmacist.

E. If the pharmacist is absent less than five minutes from the prescription department, this absence is not considered a "temporary absence" within the meaning of this Chapter and will not require a posted notice, provided the prescription department's security is not compromised.

F. If at any time the pharmacist deems it necessary to leave the on-site facility, the pharmacy shall be closed in accordance with §1111.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 27:2237 (December 2001), amended LR 29:2088 (October 2003), effective January 1, 2004.

§1111. Pharmacist Absence

A. A pharmacist is considered absent from the prescription department when he is not in the prescription department and is off-site.

B. When a pharmacist is absent from the prescription department, the prescription department must be securely closed and made inaccessible. A sign shall be displayed in a conspicuous position in front of the prescription department giving notice of closure. The sign shall be at least 8 1/2 x 11 inches with the following wording in black letters at least 1 inch high: PRESCRIPTION DEPARTMENT CLOSED.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 24:692 (April 1998), amended LR 29:2089 (October 2003), effective January 1, 2004.

§1113. Mechanical Drug Dispensing Devices

A. Dispensing of prescription drugs directly to a patient or caregiver by mechanical devices or machine is prohibited. This prohibition shall not apply to automated medication systems as defined and provided for in Chapter 12 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004.

§1115. Advertising

A. False, fraudulent, deceptive, or misleading advertising as prohibited by R.S. 37:1241 of the Pharmacy Practice Act and this Section shall include, but is not limited to, any public misrepresentation done or made with the knowledge, whether actual or constructive, that is untrue or illegal, or is said to be done falsely when the meaning is that the party is in fault for its error. Actual or constructive knowledge as used in this context shall include intentionally, negligently, mistakenly, or accidentally representing an untrue fact.

B. No person shall carry on, conduct, or transact business under a name which contains a part thereof the words "pharmacist", "pharmacy", "apothecary", "apothecary shop", "chemist's shop", "drug store", "druggist", "drugs", or any word or words of similar or like import, or in any manner by advertisement, circular, poster, sign, or otherwise describe or refer to a place of business by the terms of "pharmacy", "apothecary", "apothecary shop", "chemist's shop", "drug store", "drugs", or any word or words of similar or like import, unless the place of business is a pharmacy validly permitted by the board.

C. Pharmacies and pharmacists are prohibited from advertising professional ability, experience, integrity, professional qualifications, or soliciting professional practice by means of providing prescribers of prescriptions with prescription forms imprinted with any material referring to a pharmacy or pharmacist.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004.

§1117. Centralized Prescription Processing

A. Centralized prescription processing is the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.

B. Labeling. All drugs dispensed to a patient that have been filled via a centralized prescription processing system shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmacy primary care activities.

C. Requirements

1. A pharmacy may only perform or outsource centralized prescription processing services provided the parties involved:

a. have the same owner; or

b. have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations, and share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a prescription drug order.

2. The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedure manual and documentation that implementation is occurring in a manner that shall be made available to the board for review upon request and that includes the following:

a. the maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling processes;

b. the maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process;

c. the maintenance of a mechanism to identify on the prescription label all pharmacies involved in dispensing the prescription drug order; and

d. the provision of adequate security to protect the confidentiality and integrity of patient information.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004.

Subchapter B. Pharmacy Records

§1119. Availability and Inspection

A. Pharmacy records shall be available and readily retrievable upon request for board inspection and review.

B. All records required by the laws and regulations of the board shall be provided to the board, or its agent, within 72 hours of request, unless a shorter period is required, as determined by the board or its agent.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004.

§1121. General Record Keeping

A. Requirements. A pharmacy shall maintain complete, accurate, and readily retrievable prescription drug records. All prescription drug records shall be available for board review upon request.

B. Accountability. The holder of the pharmacy permit and the pharmacist-in-charge shall account for all prescription drug transactions, consisting of:

1. acquisition records—invoice receipts of drugs acquired;

2. disposition records—prescription orders dispensed or drugs sold; and

3. inventory records—drugs in current possession.

C. Retention. All records required in this Section and by Louisiana law shall be retained for a minimum of two years.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004.

§1123. Records

A. Acquisition Records. Prescription drug acquisition records shall be required, and shall consist of documented invoices from manufacturers, wholesalers, distributors, brokers, or other sources of supply.

B. Inventory Records. Accurate and readily retrievable records regarding prescription drug acquisition invoices, distribution, and inventories shall be maintained and available for accountability and retained at the pharmacy premises. Inventories of controlled dangerous substances shall be required, where applicable, and maintained at the pharmacy.

C. Prescription Records

1. Dispensing Prescription Files. Dispensed prescription orders shall be required and maintained for a minimum of two years from the last transaction/fill date by the pharmacy, constituting proof of dispensing by adequate prescription files properly documented with the proper medical practitioner's authority and the following information:

a. patient's name, address, and telephone number;

b. prescriber's name, address, telephone number and, if applicable, the Drug Enforcement Administration (DEA) registration number and signature;

c. drug name, dosage form, strength, and quantity prescribed, as well as quantity dispensed when in variance with the original order;

d. number of prescription refills authorized by the prescriber;

e. prescription number;

f. original dispensing date; and

g. pharmacist's name or initials.

2. Prescription Refill Records. The following information shall be readily retrievable from the electronic record keeping system:

a. date of refill;

b. quantity dispensed when in variance with original order; and

c. pharmacist's name, initials, or identification code.

D. Electronic Record Keeping System. An electronic record keeping system shall be utilized in a pharmacy and shall be a complete, accurate, readily retrievable prescription record keeping and storage system. An electronic record keeping system shall meet the following requirements.

1. Retrieval. The system shall provide on-line retrieval via screen or hard-copy printout of original prescription order information for those prescription orders that are currently authorized for refilling.

2. Summary. The system shall be capable of producing a daily hard-copy summary of controlled dangerous substance transactions.

3. Refills. The system shall be capable of recording and providing the dates of prescription refills and the identity of the pharmacist refilling those prescriptions.

4. Patient Profile. The system shall be capable of producing a patient profile that shall contain the following minimum information: patient's name and address/location, name of drug, dosage form, strength, route and frequency of administration, and pharmacist's identification.

5. Original Prescription Records. The prescription hard copy shall represent the original written order or original oral prescription reduced to written form manually or electronically produced by the pharmacist, and shall meet the record keeping requirements of this Chapter.

6. Maintenance. The original written prescription, or the written form of an oral prescription, shall be retained on file, in numerical order, for a minimum of two years from the date of dispensing or the date of the last refill dispensed.

7. Prescription Refill Information. Records of refills shall be entered into the electronic record keeping system.

8. Record. A report of all original or refilled prescriptions dispensed shall be maintained, and shall include the following:

a. prescription number;

b. date of initial dispensing of the original prescription and the date(s) of refilling;

c. total number of prescription refills dispensed to date or retrievable refill history on a visual mode of display as an alternative to appearing on the hard-copy printout;

d. patient's name;

e. patient's address, if required;

f. the authorized prescriber's name;

g. authorized prescriber's address, if required;

h. the name, strength, dosage form, and quantity of the drug dispensed; and

i. the last name and initial of the dispensing pharmacist.

9. Backup Support System. The electronic record keeping system shall be capable of being reconstructed in the event of an electronic or computer malfunction or unforeseen accident resulting in the destruction of the system or the information contained therein. To prevent the accidental loss of electronic records, an adequate backup system shall be maintained. Backup support systems shall be updated at least once daily.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004.

§1125. Security

A. The electronic record keeping system shall provide adequate safeguards against improper, illegal, or unauthorized manipulation or alteration.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2091 (October 2003), effective January 1, 2004.

§1127. Register

A. The pharmacy shall maintain a register in which each individual pharmacist dispensing a prescription shall sign a log each day, attesting to the fact that the information entered into the electronic record keeping system has been reviewed that day, and is correct as stated.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2091 (October 2003), effective January 1, 2004.

§1129. Confidentiality

A. A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to confidential information. If confidential health information is not transmitted directly between a pharmacist and a practitioner, but is transmitted through a data communication device, the confidential health information may not be accessed, maintained, or altered by the operator of the data communication device. Confidential information is privileged and may be released only subject to federal privacy laws and regulations, and subject to applicable Louisiana statutes.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091 (October 2003), effective January 1, 2004.

Subchapter C. Pharmacy Opening, Closing, Change of Ownership, and Change of Location Procedures

§1131. Pharmacy Opening Procedures

A. The board has established the following procedures as a prerequisite to the opening of any pharmacy.

1. Application Form. The applicant shall obtain a Pharmacy Permit Application and Louisiana Controlled Dangerous Substance License Application from the board. The completed form(s) shall be signed by the pharmacist-in-charge and returned to the board office, with appropriate fees, not less than 30 days prior to the anticipated opening of the pharmacy.

2. Inspection. After the board has reviewed and approved the application, a board compliance officer shall conduct an on-site inspection of the premises.

3. Compliance. Upon receipt of satisfactory evidence that the applicant is in complete compliance, the board shall issue a pharmacy permit and, if requested, a Louisiana Controlled Dangerous Substance License.

4. DEA Registration. If applicable, the applicant shall obtain the appropriate application from the DEA, and then return said form, with appropriate fees, to the DEA.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091 (October 2003), effective January 1, 2004.

§1133. Pharmacy Closing Procedures

A. A pharmacy permit holder shall notify the public and the board prior to discontinuing a prescription department operation, or upon petitioning for bankruptcy.

1. Public Notice. The holder of a pharmacy permit shall post a closing notice in a conspicuous place in the front of the prescription department, and at all public entrance doors to the pharmacy. The closing notice to the public shall be posted not less than 10 days prior to the anticipated date of closure, and the notice shall contain the following minimum information:

a. the anticipated date of closure of the prescription department;

b. the anticipated date of transfer or relocation of prescription files, if different than closure date;

c. the name and address of the pharmacy to which the prescription files will be transferred; and

d. a statement that if a patient objects to the transfer of their prescription files to the intended recipient pharmacy, the patient shall make alternative arrangements for the transfer of their prescription files to another pharmacy prior to the anticipated file transfer date.

2. Board Notice. The holder of a pharmacy permit shall send written notice to the board not less than 10 days prior to the anticipated date of closure, and the notice shall include the following minimum information:

a. the anticipated date of closure of the prescription department;

b. the name and address of the permitted pharmacy operating within a reasonably close proximity of the closing pharmacy that shall be the custodian of the transferred prescription files; and

c. any prescription drug sale or transfer, with a complete drug inventory including recipient's name and address and/or seizure action, sequestration, executory process, public auction, liquidation, creditor assignment, and bankruptcy.

3. Disposition of Inventory

a. Drugs Listed in Schedule II. These drugs shall be either returned to the supplier or transferred to an authorized registrant, accompanied by an executed DEA Form 222, or its successor. Alternatively, these drugs shall be inventoried on the DEA Form 41 (Registrants Inventory of Drugs Surrendered), or its successor, and then either returned to the regional DEA office, or destroyed pursuant to permission from the DEA or agent of the board. The permit holder shall retain triplicate copies of returns, transfers, and/or destructions.

b. Drugs Listed in Schedules III, IV, or V. These drugs shall be either returned to the supplier or transferred to an authorized registrant, accompanied by appropriate inventory records. Alternatively, these drugs shall be inventoried on the DEA Form 41, or its successor, and then either returned to the regional DEA office, or destroyed pursuant to permission from the DEA or agent of the board.

c. All Other Prescription Drugs. These drugs shall be returned to the supplier, transferred to an authorized registrant, or destroyed.

4. Surrender of Pharmacy Permit and Louisiana Controlled Dangerous Substance License. The holder of the permit and license shall surrender same to the board upon closing, accompanied by written confirmation of the:

a. surrender of unused DEA order forms and the DEA registration certificate to the regional DEA office with a memorandum indicating the closing date of the prescription department;

b. location of applicable records of controlled dangerous substance and other prescription drugs, order forms, inventories, acquisitions, and purchase records, with commitment to store such records for not less than two years, and to make such records available for inspection by an agent of the board; and

c. removal of all pharmacy signage from the property.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091 (October 2003), effective January 1, 2004.

§1135. Pharmacy Change of Ownership Procedures

A. The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises.

1. A change of ownership of a pharmacy is evident under the following conditions:

a. sale of a pharmacy;

b. death of a sole proprietor;

c. the addition or deletion of one or more partners in a partnership;

d. bankruptcy sale; or

e. a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

2. The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

3. Upon receipt of the new permit, the seller shall:

a. notify the board of the transaction, including the identity of the new owner(s);

b. surrender the DEA registration certificate to the regional DEA office, indicating the date of the change in ownership of the prescription department; and

c. surrender the voided pharmacy permit and voided Louisiana Controlled Dangerous Substance License to the board.

4. Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2092 (October 2003), effective January 1, 2004.

§1137. Pharmacy Change of Location Procedures

A. The board has established the following procedures for changing the location of any pharmacy that does not involve a change of ownership or divestiture of that pharmacy.

1. The permit holder shall notify the board in writing prior to relocating a prescription department operation.

2. The proper notice procedures for the relocation shall include the notice requirements applicable to pharmacy closing procedures noted in this subpart. However, a permit cancellation is not required for a permit holder that is moving to a location in reasonably close proximity to the original location and planning to continue pharmacy operations without a transfer of ownership. The permit holder shall notify the board for the proper re-designation of permit address and re-issuance of that same permit.

3. Inspection. A board compliance officer shall conduct an on-site inspection of the premises following receipt of written notice in the board office and prior to the opening of a prescription department in a new location.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2092 (October 2003), effective January 1, 2004.

Chapter 12. Automated Medication Systems

§1201. Definitions

Automated Medication System—includes, but is not limited to, a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, or delivery of medications, and which collects, controls, and maintains all transaction information. An *automated medication system* may be *profile driven*, *non-profile driven*, or a combination of both.

Final Checks of Work—the requirement that only a pharmacist supervises and releases the completed product prepared by a pharmacy technician.

Floor Stock/First Dose Cabinet—a medication storage device, which shall be used by personnel, authorized by a protocol established by the pharmacist-in-charge, to gain access to doses as needed and first doses in patient care areas. In addition, a *floor stock/first dose cabinet* may be used to store medications in such specialty areas including, but not limited to emergency room, surgery suite, and endoscopy suites.

Non-Profile Driven—system does not require prior or concomitant pharmacist review of medication order/prescriptions in order to gain access to the system for medication administration. A *non-profile driven* system may include, but is not limited to, a night drug cabinet, emergency drug kits, or *floor stock/first dose cabinet*.

Off-Site Facility—the location of a building that houses a licensee of the Department of Health and Hospitals, but which does not house a board permitted pharmacy.

On-Site Facility—the location of a building that houses a board permitted pharmacy.

Profile Driven—system requires that medication orders/prescriptions be reviewed by the pharmacist for appropriateness, dosage, and contraindications prior to, or concomitantly with, being entered into the system, and before access is allowed into the system for medication administration.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000), effective July 1, 2000.

§1203. System(s) Registration

A. The entire system shall be registered with the board and facilities shall meet the following conditions.

1. Facility shall possess a:

a. license from the Health Standards Section of the Department of Health and Hospitals; or

b. Controlled Dangerous Substance License from the Health Standards Section of the Department of Health and Hospitals; or

c. permit from the board.

2. Registration fee for a facility not permitted by the board is as identified in R.S. 37:1184.C.xii.

3. No registration fee will be assessed to a board permitted pharmacy.

4. Registration expires annually on June 30.

5. Initial application shall be completed and signed by the registrant of the facility and the pharmacist-in-charge of the system(s). The completed, signed application and required fee shall be submitted to the board office no later than 30 days prior to installation of the system.

6. Annual Renewal. The board shall mail an application for renewal to each registrant on or before May 1 each year. Said application shall be completed, signed, and, with annual renewal fee, returned to the board office to be received on or before June 1 each year.

7. Expired Registration. A registration that is not renewed shall be null and void. A renewal application for an expired registration shall be requested by the registrant and the completed, signed application may be referred to the board's reinstatement committee for disposition in accordance with R.S. 37:1230.

8. Reinstatement. The holder of a registration that has expired may be reinstated only upon written application to the board and upon payment of all lapsed fees and a penalty to be fixed by the board. Other conditions of reinstatement may be required at the discretion of the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000), effective July 1, 2000.

§1205. Pharmacist-in-Charge Responsibilities

A. The pharmacist-in-charge shall be a Louisiana licensed pharmacist and has the following responsibilities:

1. assuring that the system is in good working order and accurately provides the correct strength, dosage form and quantity of the drug prescribed while maintaining appropriate record-keeping and security safeguards;

2. establishment of a quality assurance program prior to implementation of a system and the supervision of an ongoing quality assurance program that monitors appropriate use and performance of a system, which is evidenced by written policies and procedures developed by the pharmacist-in-charge;

3. provide 30 days written notice to the board of removal of the system;

4. define access to the system in policy and procedures of the pharmacy, in compliance with state and federal regulations;

5. assign, discontinue or change access to the system;

6. ensure that access to the medications complies with state and federal regulations as applicable; and

7. ensure that the system is stocked/restocked accurately and in accordance with established written pharmacy policies and procedures;

8. maintain or have access to all records of documentation specified in this Section for two years or as otherwise required by law;

9. notify each licensed prescriber that his medication orders/prescriptions are not restricted to the limited number of medications which are stocked within a facility's automated medication system by placing a prominent notice to that effect on the cover of or near the beginning of such patient's medical chart or medical record.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000), effective July 1, 2000.

§1207. Pharmacist Review

A. System shall be used in settings that ensure medication orders are reviewed by a pharmacist prior to administration and in accordance with established policies and procedures and good pharmacy practice. A policy and procedure protocol shall be adopted to retrospectively review medications which cannot be reviewed prior to administration, as provided in LAC 46:LIII.1209.A.2.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1272 (June 2000), effective July 1, 2000.

§1209. Policies and Procedures

A. The development of an automated medication system policy and procedures is the responsibility of the pharmacist-in-charge, who shall submit the complete automated medication system policy and procedures to the board for approval, on request. These policies and procedures shall be reviewed by the pharmacist-in-charge, at least annually and modified if needed, and such review documented. They shall include, but are not limited to, the following:

1. criteria for selection of medications to be stored in each system, provided that, in facilities licensed by the Department of Health and Hospitals but not by the board, the selection criteria shall not include the substitution by the pharmacist of a product that is not an equivalent drug product to the product originally prescribed by the physician or practitioner without the explicit consent of the physician or practitioner;

2. criteria for medications qualifying for use with a non-profile driven system and the locations and situations that this type of system can be used in;

3. information on the system as outlined below:

a. access:

i. system entry;

ii. access codes;

iii. system access privileges;

iv. changing access privileges;

v. termination of user;

vi. temporary access codes;

vii. password assignment;

b. controlled substances:

i. chain of custody;

ii. discrepancy resolution;

c. data:

i. archiving;

ii. stored/uploading to database;

iii. backup;

d. definitions;

e. downtime procedures (see malfunction);

f. emergency procedures;

g. information security/confidentiality:

i. patient information;

ii. medication information;

iii. transaction files;

iv. information update plan;

v. patient update plan;

vi. information access;

h. inspection;

i. installation requirements;

j. maintenance, e.g., service and repair protocols;

k. medication administration:

i. medication and patient validation;

ii. administration verification;

l. medication security:

i. acquisition and disposition records;

ii. proof of delivery;

iii. chain of custody of controlled substances (institutions);

iv. security management and control;

v. medication loading and storage;

vi. medication loading records;

vii. medication containers;

viii. cross contamination;

ix. lot number control;

x. inventory;

xi. utilization review;

xii. research;

m. malfunction:

i. troubleshooting;

ii. power failure;

n. quality assurance/quality improvement:

i. documentation and verification of proper loading and refilling of device;

ii. removal of drugs for administration, return, or waste;

iii. recording, resolving, and reporting of discrepancies;

iv. periodic audits to assure compliance with policies and procedures;

o. reports:

i. system maintenance;

ii. administrative functions;

iii. inventory;

iv. error;

v. discrepancies;

vi. activity;

vii. problem;

p. medication inventory:

i. management;

q. staff education and training;

r. system set-up.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy LR 26:1272 (June 2000), effective July 1, 2000.

§1211. Documentation

A. Documentation as to type of equipment, serial number, content, policies and procedures and location shall be maintained on-site in the pharmacy for review by the board. Such documentation shall include, but is not limited to:

1. name, address, and permit number of the pharmacy or licensed health care facility where the system is operational;

2. manufacturer's name and model;

3. quality assurance policies and procedures to determine continued appropriate use and performance of the system;

4. policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, controlled substances, data retention, definitions, downtime procedures, emergency or first dose procedures, inspection, installation requirements, maintenance security, quality assurance, medication inventory, staff education and training, system set-up and malfunction procedures; and

5. a current copy of all pharmacy policies and procedures related to the use of the system shall be maintained at all off-site facility locations where the system is being used, as well as the pharmacy of the pharmacist-in-charge.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1272 (June 2000), effective July 1, 2000.

§1213. Records

A. Records and/or electronic data kept by system shall meet the following requirements:

1. all events involving access to the contents of the system shall be recorded electronically;

2. these internal records shall be maintained for one year by the pharmacist-in-charge and shall be readily available to the board. Such records shall include:

a. identity of system accessed;

b. identification of the individual accessing the system;

c. type of transaction;

d. name, strength, dosage form, and quantity of the drug accessed;

e. name of the patient, or identification numbers for whom the drug was ordered;

f. identification of the certified pharmacy technician or pharmacist stocking or restocking the medications in the system; and

g. such additional information as the pharmacist-in-charge may deem necessary.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1273 (June 2000), effective July 1, 2000.

§1215. Security System(s)

A. System shall have adequate security system and procedures, evidenced by written pharmacy policies and procedures, to:

1. prevent unauthorized access or use;

2. comply with any applicable federal and state regulations; and

3. maintain patient confidentiality.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1273 (June 2000), effective July 1, 2000.

§1217. Stocking and Restocking

A. On-Site Facility System(s). The stocking and restocking of all medications in the on-site system shall be accomplished by Louisiana licensed pharmacists and/or Louisiana certified pharmacy technicians under the supervision of Louisiana licensed pharmacists. A pharmacist must conduct final checks of work performed by a pharmacy technician. The pharmacy shall have a mechanism in place to identify the certified pharmacy technician stocking or restocking and the pharmacist checking the accuracy of the medications to be stocked or restocked in the Automated Medication Systems.

B. Off-Site Facility System(s). The stocking and restocking of all medications in the off-site system shall be accomplished by Louisiana licensed pharmacists; however, the certified pharmacy technician may stock or restock an off-site facility system provided a pharmacist is physically present at the off-site facility and supervises and verifies the stocking and/or restocking prior to use. The pharmacy shall have a mechanism in place to identify the certified pharmacy technician stocking or restocking and the pharmacist checking the accuracy of the medications to be stocked or restocked in the system.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1273 (June 2000), effective July 1, 2000.

§1219. Packaging and Labeling

A. All containers of medications stored in the system shall be packaged and labeled in accordance with federal and state laws and regulations and contain an established satisfactory beyond use date based on U.S.P. standards.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1273 (June 2000), effective July 1, 2000.

§1221. Proof of Use

A. For medication removed from the system for patient administration, the system shall document, at a minimum, the following information:

1. name of the patient or resident;

2. patient's or resident's medical record number or identification number, or room and bed number;

3. date and time medication was removed from the system;

4. name, initials, or other unique identifier of the person removing the drug;

5. name, strength, and dosage form of the medication or description of the medical device removed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1273 (June 2000), effective July 1, 2000.

§1223. Wasted, Discarded, or Unused Medications

A. The system shall provide a mechanism for securing and accounting for wasted, discarded, or unused medications removed from the system according to policies and procedures, and existing state and federal law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1273 (June 2000), effective July 1, 2000.

§1225. Inspection

A. System records shall be available and readily retrievable for board inspection and review during regular working hours of operation. The system itself is also subject to inspection at that time.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1273 (June 2000), effective July 1, 2000.

§1227. Out-of-State Pharmacies

A. Out-of-state pharmacies must have applied for and been issued an out-of-state pharmacy permit by the board as identified in regulations. Out-of-state pharmacies must have the proper pharmacy permit issued by the state in which they reside in order to utilize a system in Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1274 (June 2000), effective July 1, 2000.

§1229. Violations; Penalties

A. The board may refuse to issue or renew, or may revoke, summarily suspend, suspend, place on probation, censure, reprimand, issue a warning against, or issue a cease and desist order against, the licenses or the registration of, or assess a fine/civil penalty or costs/administrative costs against any person pursuant to the procedures set forth in R.S. 37:1245, for any violation of the provisions of this Section.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1274 (June 2000), effective July 1, 2000.

§1231. Revised Statutes and Louisiana Administrative Code

A. These regulations shall be read and interpreted jointly with Chapter 14 of Title 37 of the Revised Statutes and Part LIII of Title 46 of the *Louisiana Administrative Code*.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1274 (June 2000), effective July 1, 2000.

Chapter 13. Community Pharmacy

1301. Definition

A. A *community pharmacy* is a pharmacy located in a non-institutional environment, and is licensed by the board to conduct professional pharmacy practice activities in the state of Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2092 (October 2003), effective January 1, 2004.

§1303. Permit

A. A community pharmacy permit shall be required to operate a pharmacy in this state, and to dispense prescription drugs to patients in Louisiana. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2092 (October 2003), effective January 1, 2004.

§1305. Compliance

A. A community pharmacy shall comply with all applicable federal and state pharmacy laws and regulations, including Chapter 11 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2092 (October 2003), effective January 1, 2004.

Chapter 15. Hospital Pharmacy

§1501. Cross References

A. For all regulations that apply to permitted hospital pharmacies concerning pharmacy practices not specifically stated in this Chapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004.

§1503. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section.

Hospital Pharmacy—a pharmacy department permitted by the board and located in a hospital licensed pursuant to R.S. 40:2100 et seq. For the purposes of this Chapter, a *hospital pharmacy* is one example of a primary care treatment modality pharmacy.

Registered Patient—a person receiving health care services within a hospital facility.

Unit Dose—the packaging of individual prescription doses in a suitable container that have been properly labeled as to the identity of the generic, chemical, or trade name of the drug; strength; lot number; and expiration date. All *unit doses* qualify as "prepackaging" as used in this Chapter. However, all prepackaging is not necessarily in *unit dose* packaging.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004.

§1505. Hospital Pharmacy Permit

A. A hospital pharmacy permit shall be required to operate a pharmacy department located within a hospital for registered patients in that hospital. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004.

§1507. Pharmacist-in-Charge

A. The pharmacist-in-charge of a hospital pharmacy permit shall have had at least two years of experience as a licensed and practicing pharmacist prior to accepting the appointment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004.

§1509. Drug Distribution Control

A. The hospital pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, distribution, control, accountability, and patient

administration and management of drugs. The staff of the hospital facility shall cooperate with the pharmacist-in-charge in meeting drug control requirements in ordering, administering, and accounting for pharmaceuticals.

1. Procedure Manual. The pharmacist-in-charge shall maintain written procedures for the safe and efficient distribution of pharmaceutical products and delivery of pharmacy care. An updated copy shall be available for board inspection upon request.

2. Inventories. The pharmacist-in-charge shall:

a. perform an annual inventory on all controlled dangerous substances; and

b. maintain a perpetual inventory of Schedule I and II controlled dangerous substances.

3. Records. The pharmacist-in-charge shall maintain adequate records regarding the use and accountability of controlled dangerous substances. Proof of use records for controlled dangerous substances shall be maintained separately and in such a manner as to be readily retrievable. These records shall specify the following minimum information:

a. drug name, strength, and quantity;

b. dose;

c. full name of patient;

d. date and time of administration; and

e. name of person administering the drug.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004.

§1511. Prescription Drug Orders

A. The pharmacist shall review the practitioner's medical order prior to dispensing the initial dose of medication, except in cases of emergency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004.

§1513. Labeling

A. All drugs dispensed by a hospital pharmacy, intended for use within the facility, shall be dispensed in appropriate containers and adequately labeled as to identify patient name and location, drug name(s) and strength, and medication dose(s). Additionally, compounded preparations and sterile preparations shall be labeled with the expiration or beyond-use date, initials of the preparer, and the pharmacist performing the final check.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004.

§1515. Ambulance Service Drugs

A. Hospital pharmacies that supply prescription drugs, including any controlled dangerous substances, to any authorized ambulance service or emergency medical service shall maintain proper records to ensure control, proper utilization, inventory, and accountability.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004.

§1517. Pharmacist Absence/Drug Cabinet

A. Pharmacist Absence. In the absence of a licensed pharmacist, admittance to the pharmacy by unauthorized persons is prohibited. When the pharmacy is closed, a pharmacist shall be on emergency call.

B. Drug Cabinets. In the absence of a licensed pharmacist, arrangements shall have been formulated in advance by the pharmacist-in-charge to provide drugs for the patients by the use of drug cabinets.

1. Emergency Use. A drug cabinet is solely intended for the proper and safe storage of needed drugs when the pharmacy is closed and shall be available for emergency use by authorized hospital personnel only.

2. Security. The drug cabinet shall be a securely constructed and locked enclosure located outside the permitted pharmacy ensuring access to authorized personnel only.

3. Inventory. The pharmacist-in-charge shall be responsible for the selection and quantity of the drugs to be maintained in the drug cabinet and shall maintain a perpetual inventory of any controlled dangerous substances stored in the drug cabinet.

4. Labeling. Medications stored in a drug cabinet shall be properly labeled.

5. Quantities. Prepackaged drugs shall be available in amounts sufficient for immediate therapeutic or emergency requirements.

6. Accessibility. Written medical practitioner's orders and proof of use, if applicable, shall be provided when a drug cabinet inventory is utilized.

7. Inspection. Medications stored in a drug cabinet shall be inspected every 30 days.

8. Policy Manual. A policy and procedure manual shall be maintained to implement the drug cabinet requirements and is to be made available to the board upon request for inspection and approval.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004.

§1519. Drug Returns

A. In a hospital with a permitted hospital pharmacy on site, drugs may be returned to the pharmacy in accordance with good professional practice standards.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094 (October 2003), effective January 1, 2004.

§1521. Off-Site Pharmacy Services

A. Availability. Pharmacy services may be procured contractually from outside the hospital for inpatient administration.

B. Contractual agreements shall provide for:

1. emergency—the pharmacy provider shall be available for on-call for emergency pharmacy services;

2. storage—adequate drug storage facilities shall be provided to the pharmacy provider;

3. labeling—prescription drugs supplied to hospital inpatients shall be properly labeled to ensure that adequate control, supervision, and recall of medication are monitored;

4. contractual pharmacy service—off-site contractual pharmacy services rendered to the hospital shall be in accordance with federal and state laws, rules, and regulations.

C. A pharmacy providing off-site contractual pharmacy services to a hospital shall not be considered a hospital pharmacy.

D. Medications. Prescription medications independently supplied to registered patients shall comply with all appropriate board regulations and statutes and/or hospital rules, regulations, and policies.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094 (October 2003), effective January 1, 2004.

§1523. Outpatient Pharmacy Dispensing

A. Hospital outpatient dispensing shall require a separate pharmacy permit for the specialty classification(s) under these regulations. All records including the annual inventory of controlled dangerous substances for the outpatient pharmacy shall be maintained and kept separate and apart from that of the inpatient pharmacy, as the outpatient pharmacy may not acquire drugs through the hospital pharmacy permit under the provisions of the Robinson-Patman Act, 15 U.S.C. §13(c).

B. Nothing in this Section shall prohibit the dispensing of certain prescriptions from the hospital pharmacy, as allowed under the Robinson-Patman Act, 15 U.S.C. §13, including:

1. dispensing to the hospital inpatient for use in his treatment at the hospital;

2. dispensing to the patient admitted to the hospital's emergency facility for use in the patient's treatment at that location;

3. dispensing to the hospital outpatient for personal use on the hospital premises;

4. dispensing in the context of a genuine take-home prescription, intended for a limited and reasonable time as a continuation of, or supplement to, the treatment that was administered at the hospital to the recipient while an inpatient, an outpatient, or an emergency facility patient if the patient needs that treatment; or

5. dispensing to the hospital's physicians, employees, or its students for their personal use or for the personal use of their dependents.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094 (October 2003), effective January 1, 2004.

Chapter 17. Institutional Pharmacy

Subchapter A. General Requirements

§1701. Cross References

A. For all regulations that apply to permitted institutional pharmacies concerning pharmacy practices not specifically stated in this Chapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2094 (October 2003), effective January 1, 2004.

§1703. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section.

Institutional Facility—any organization whose primary purpose is to provide a physical environment for a patient to obtain health care services, including but not limited to a(n):

a. convalescent home;

b. nursing home;

c. extended care facility;

d. mental health facility;

e. rehabilitation center;

f. psychiatric center;

g. developmental disability center;

h. drug abuse treatment center;

i. family planning clinic;

j. penal institution;

k. hospice;

l. public health facility;

m. athletic facility.

Institutional Pharmacy—that physical portion of an *institutional facility* where drugs, devices, and other materials used in the diagnosis and treatment of an injury, illness, and disease are dispensed, compounded, and distributed and pharmacy primary care is provided, and is permitted by the board and is devoted exclusively to providing professional services to a patient in that institutional setting, other than a hospital.

Long Term Care Facility—a nursing home, retirement center, mental care, or other facility or institution that provides extended health care to a residential patient, including but not limited to health care facilities licensed by the Department of Health and Hospitals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2094 (October 2003), effective January 1, 2004.

§1705. Institutional Pharmacy Permit

A. An institutional pharmacy permit shall be required to operate a pharmacy department located within an institutional facility, other than a hospital, for residents or patients of that institutional facility. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2095 (October 2003), effective January 1, 2004.

§1707. Drug Cabinet

A. In the absence of a licensed pharmacist, arrangements shall have been formulated in advance by the pharmacist-in-charge to provide drugs for the residents/patients by the use of drug cabinets. When the pharmacy is closed, a pharmacist shall be on emergency call.

1. Emergency Use. A drug cabinet is solely intended for the proper and safe storage of needed drugs when the pharmacy is closed and shall be available for emergency use by authorized facility personnel only.

2. Security. The drug cabinet shall be a securely constructed and locked enclosure located outside the permitted pharmacy area ensuring access by authorized personnel only.

3. Inventory. The pharmacist-in-charge shall be responsible for the selection and quantity of drugs to be maintained in the drug cabinet and shall maintain a perpetual inventory of any controlled dangerous substances. Medications shall be available in quantities sufficient only for immediate therapeutic needs.

4. Labeling. Medications stored in a drug cabinet shall bear a label with the following minimum information:

a. drug name;

b. dosage form;

c. strength;

d. name of manufacturer and/or distributor;

e. manufacturer's lot or batch number;

f. pharmacist's initials; and

g. expiration date, according to United States Pharmacopeia guidelines.

5. Accountability. Documented medical practitioner's orders and proof of use shall be provided when any of the drug cabinet inventory is utilized.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2095 (October 2003), effective January 1, 2004.

Subchapter B. Emergency Drug Kits

§1709. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section:

Emergency Drug Kit (EDK)—for long-term care facilities or other board-approved sites, other than a hospital, means a drug kit containing designated *emergency drugs* which may be required to meet the immediate therapeutic needs of a resident or patient.

Emergency Drugs—those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients or residents because of delay resulting from obtaining such medications from such other source.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2095 (October 2003), effective January 1, 2004.

§1711. Emergency Drug Kit Permit

A. A long-term care facility, institutional facility without an institutional pharmacy, or other board-approved site, other than a hospital, that desires to maintain an Emergency Drug Kit shall obtain an EDK permit from the board.

B. Permit Application and Requirements. Application for an EDK permit shall be made on a form provided by the board.

1. The provider pharmacy shall apply to the board for an EDK permit. The administrator of the applicant facility shall also sign the application for said permit. Upon compliance with the required provisions, the provider pharmacy shall be issued a permit by the board for the provider pharmacy to establish and maintain an EDK in the facility.

2. The provider pharmacy shall be a Louisiana-licensed pharmacy.

3. Only one provider pharmacy shall be assigned to and be responsible for each EDK.

4. EDK permits are institutional facility-specific and not transferable.

5. A separate permit is required for each EDK.

6. The original EDK permit shall be conspicuously displayed at the provider pharmacy. A copy of the EDK permit shall be maintained in the room where the EDK is located.

C. Pharmacist-in-Charge. The pharmacist-in-charge of the provider pharmacy shall be the pharmacist-in-charge of the EDK. The maintenance of the EDK shall at all times remain the responsibility of the pharmacist-in-charge.

D. Renewal. Each EDK permit issued by the board shall be renewed annually by the provider pharmacy, at the time designated by the board. If an EDK permit is not renewed by July 1 of each year, the existing permit shall expire and become null and void.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2095 (October 2003), effective January 1, 2004.

§1713. Emergency Drug Kit Requirements

A. Emergency Use. An EDK is solely intended for the immediate therapeutic emergency needs of a resident or patient.

B. Security. The EDK shall be tamper-evident and shall be maintained in a secure enclosure located within the institutional facility and shall be available for emergency use by authorized personnel only.

C. Exterior Identification and Labeling. The EDK shall be clearly labeled to indicate that it is an emergency drug kit. In addition, the attached exterior label shall have an inventory of contents and contact information of the provider pharmacy.

D. Labeling. Medications stored in an EDK shall bear a label with the following minimum information:

1. drug name;

2. dosage form;

3. strength;

4. name of manufacturer and/or distributor;

5. manufacturer's lot or batch number; and

6. expiration date, according to United States Pharmacopeia guidelines.

E. Storage. All drugs in an EDK shall be stored to ensure a proper environment for the preservation of the drugs. If federal or state laws or regulations require adequate storage outside the EDK, documentation shall be kept with the EDK properly identifying this special storage requirement and drug(s) involved.

F. Policies and Procedures. Policies and procedures shall be maintained by the provider pharmacy and the applicant facility to implement the EDK requirements.

G. Accountability. Documented medical practitioner's orders and proof of use shall be provided when an EDK inventory is utilized. Medication administered to patients from the EDK shall be documented with the following information, in accordance with the institutional facility policy manual, that shall be immediately reduced to writing and a copy delivered to the provider pharmacy:

1. name of the resident patient;

2. drug name, strength, and quantity;

3. nature of the emergency;

4. time and date of administration;

5. name of person administering the medication; and

6. name of prescriber authorizing the medication.

H. Records. Records shall be readily retrievable and comply with applicable federal and state laws and regulations.

I. Inspection

1. The provider pharmacy shall inspect the EDK every 30 days, plus or minus five days. Proper documentation of these inspections, EDK inventory, and all records of use shall be maintained and made available to the board upon request.

2. The EDK shall be available for inspection by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004.

Subchapter C. Drug Abuse Treatment Center Pharmacies

§1715. Purpose

A. The board may issue a pharmacy permit for a drug abuse treatment center operating in the state of Louisiana where drugs are dispensed and pharmacy primary care is provided.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004.

§1717. Cross References

A. For all regulations that apply to drug abuse treatment center pharmacies concerning pharmacy practices not specifically stated in this Subchapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004.

§1719. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section.

Administer or Administration—the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

Authorized Personnel—individuals who, within the scope of their authority granted by mutual agreement of the *drug abuse treatment center*'s pharmacist-in-charge and director, are granted access to the *drug abuse treatment center*'s pharmacy department as part of his duties.

Dispense or Dispensing—the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. *Dispense* necessarily includes a transfer of possession of a drug or device to the patient or the patient's agent.

Drug Abuse Treatment Center—any establishment, facility, or institution, public or private, whether operated for profit or not, which primarily offers, or purports to offer, maintain, or operate facilities for the residential or outpatient diagnosis, care, treatment, or rehabilitation of two or more non-related individuals, who are patients as defined herein, excluding, however, any hospital or mental hospital otherwise licensed by the Department of Health and Hospitals.

Patient or Client—a person who is dependent on, or otherwise suffering physically or mentally from the use of, or abuse of, controlled dangerous substances and who requires continuing care of a *drug abuse treatment center*.

Perpetual Inventory—a computer record of inventory kept continuously up to date by detailed entries of all incoming and outgoing items. This includes inventory on hand, purchases, and dispensing.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004.

§1721. Drug Abuse Treatment Center Pharmacy Permit

A. A drug abuse treatment center pharmacy permit shall be required to operate a pharmacy department located within a drug abuse treatment facility for patients of that facility. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2097 (October 2003), effective January 1, 2004.

§1723. Minimum Security Controls for Drug Abuse Treatment Centers

A. Persons enrolled in a drug abuse treatment center shall wait for their prescriptions in an area physically separated from the controlled dangerous substance (CDS) storage and dispensing area. This requirement shall be enforced by the drug abuse treatment center physician(s), pharmacist(s), and employees.

B. All CDS used in a drug abuse treatment center shall be securely locked and accessible to authorized personnel within that facility only.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2097 (October 2003), effective January 1, 2004.

§1725. Records and Reports of Drug Abuse Treatment Centers

A. All persons licensed by the Department of Health and Hospitals to operate a drug abuse treatment center and who possess a Drug Enforcement Administration (DEA) registration to purchase, possess, and use CDS shall keep the following records:

1. records of CDS received by approved persons, including date of receipt, name and address of distributor, type and quantity of such drugs received, and the signature of the individual receiving the CDS. A duplicate invoice or separate itemized list furnished by the distributor will be sufficient to satisfy this record requirement, provided it includes all required information and is maintained in a separate file. In addition, duplicate copies of federal order forms for CDS listed in Schedule II must be retained; and

2. records of CDS administered or dispensed, including date of administration or dispensing, name of patient, signature of person administering or dispensing, type and quantity of drug, and such other information as may be required by state and federal laws and regulations.

B. Records of perpetual inventories shall be kept at the permitted site as prescribed by law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2097 (October 2003), effective January 1, 2004.

Chapter 19. Nuclear Pharmacy

§1901. Cross References

A. For all regulations that apply to permitted nuclear pharmacies concerning pharmacy practices not specifically stated in this Chapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2097 (October 2003), effective January 1, 2004.

§1903. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section.

Nuclear Pharmacy—a board-approved facility limited to procuring, possessing, compounding, or dispensing *radiopharmaceuticals* or any interventional drug used in conjunction with nuclear medicine procedures. This definition shall not apply to hospital nuclear medicine departments and nuclear medicine clinics operating under the auspices of a licensed practitioner of medicine.

Radiation—any electromagnetic or ionizing *radiation* including gamma rays, X-rays, alpha and beta particles, high-speed electrons, neutrons, protons, and other nuclear particles.

Radioactive Material—any solid, liquid, or gas that emits *radiation* spontaneously.

Radiopharmaceutical—a drug that is a *radioactive material* and includes any drug that is intended to be made radioactive, as defined by the appropriate federal agency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2097 (October 2003), effective January 1, 2004.

§1905. Nuclear Pharmacy Permit Requirements

A. A nuclear pharmacy permit shall be required to operate a nuclear pharmacy department. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.

1. A nuclear pharmacy shall have a Louisiana Radioactive Material License.

2. Nuclear Pharmacist-in-Charge. A pharmacist-in-charge of a nuclear pharmacy operation shall be a qualified nuclear pharmacist, as defined in §1907, and shall be responsible for the entire nuclear pharmacy operation.

3. Structural Requirements. A nuclear pharmacy shall provide adequate space separate and apart from other areas commensurate with the scope of service and with the following space requirements.

a. Dispensing Area. The radiopharmaceutical compounding or preparation area shall be separate and apart from other facility areas and shall be not less than 300 square feet, which may include storage and decay areas. The pharmacy area shall be sufficient to provide a work environment for the safe handling, compounding, and dispensing of radiopharmaceuticals. This area shall be separate and inaccessible to non-pharmacy personnel.

b. Delivery and Receipt Area. An area designated for the delivery and receipt of materials requiring after-hours handling by non-pharmacy personnel. This area shall be separate from the dispensing area of the pharmacy.

c. Storage Area. A storage area sufficient to maintain the scope and content of unused and returned material for decay and disposal commensurate with the compounding and dispensing requirements of the facility.

d. Maintenance. A nuclear pharmacy shall be well maintained, clean, orderly, lighted, and properly ventilated.

e. Plumbing. A sink equipped with hot and cold running water shall be located within the nuclear pharmacy. A sink located in a pharmacy lavatory or restroom shall not be sufficient to satisfy this requirement.

4. Equipment. There shall be adequate equipment commensurate with the scope of services required and provided by the facility.

5. Supplies. There shall be adequate supplies commensurate with the compounding and dispensing needs of the facility, as well as any other services provided for by the facility, including appropriate shielding and safety devices and any other supplies necessary for the safe and legal transport of materials compounded or dispensed from the facility. There shall be appropriate supplies for the safe handling and disposal of used and unused material by employees and staff of the facility. The appropriateness of personal protective equipment shall be reviewed on an annual basis.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2097 (October 2003), effective January 1, 2004.

§1907. Qualified Nuclear Pharmacist

A. A qualified nuclear pharmacist shall be a currently licensed pharmacist in the state of Louisiana who is listed on a Louisiana Radioactive Material License.

B. Continuing Education. Nuclear pharmacists shall obtain at least five hours of the total required hours of American Council on Pharmaceutical Education (ACPE) or board-approved continuing education on those applications and procedures specific to nuclear pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

§1909. Labeling

A. Immediate Container. The immediate container that comes into direct contact with the radiopharmaceutical shall be labeled with:

1. the standard radiation symbol;

2. the words "Caution—Radioactive Material";

3. the prescription control number;

4. the name of the radionuclide; and

5. the amount of radioactive material contained, in the appropriate unit of measure.

B. Outer Container. In addition to any labeling requirements of the board for non-radiopharmaceuticals, the outer container of a radiopharmaceutical to be dispensed shall also be labeled with:

1. the standard radiation symbol;

2. the words "Caution—Radioactive Material";

3. the name of the radionuclide;

4. the chemical form;

5. the amount of material contained, in the appropriate unit of measure;

6. the liquid volume expressed in cubic centimeters or milliliters, where applicable; and

7. the calibration time and date for the amount of radioactivity contained.

C. The labeling requirements in this Section shall not apply to transport containers.

D. Practitioner Administered Compounds Labeling. All practitioner administered compounds, as defined in Chapter 25 of these regulations, shall be dispensed or delivered in a suitable container with a label containing the following information:

1. pharmacist's name or initials;

2. pharmacy's name, address, and telephone number;

3. preparation name;

4. prescription number or pharmacy-assigned identification number;

5. lot number;

6. beyond-use date;

7. strength and concentration;

8. practitioner's name; and

9. special storage requirements, if applicable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

§1911. Quality Control and Quality Assurance

A. Quality control of radiopharmaceuticals is required on all radiopharmaceuticals compounded in a nuclear pharmacy. Appropriate quality assurance procedures shall be developed and followed for the procurement, compounding, and dispensing of all pharmaceuticals in a nuclear pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

Chapter 21. Charitable Pharmacy

§2101. Cross References

A. For all regulations that apply to permitted charitable pharmacies concerning pharmacy practices not specifically stated in this Chapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

§2103. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section.

Charitable Pharmacy—the practice of pharmacy at a site where prescriptions are dispensed by a charitable organization free of charge to appropriately screened and qualified patients. For the purposes of the Louisiana Administrative Code and the Pharmacy Practice Act, a *charitable pharmacy* may at times also be referred to as a *provisional permitted pharmacy*.

Qualified Patients—those patients who are without sufficient funds to obtain medications as determined by strict screening guidelines based on needs assessment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

§2105. Charitable Pharmacy Permit Requirements

A. A charitable pharmacy permit shall be required to operate a pharmacy in the state to dispense free prescription drugs to qualified patients in Louisiana. This permit shall only be granted to an organization qualified as a charitable organization by the U.S. Internal Revenue Code under 26 U.S.C. §501(c)(3), or its successor.

B. Compliance. The charitable pharmacy shall be in compliance with applicable federal, state, and local laws and/or regulations pertaining to the practice of pharmacy.

C. Guidelines. Strict screening guidelines based on needs assessment shall be developed by the charitable pharmacy to determine who is eligible as a qualified patient.

D. Review. All screening guidelines, needs assessments, and revisions shall be submitted to the board upon request.

E. Patient Dispensing. Prescriptions filled in a charitable pharmacy may only be dispensed to qualified patients of that pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2099 (October 2003), effective January 1, 2004.

§2107. Prescription Drug Samples

A. A charitable pharmacy shall not sell, purchase, or trade prescription drug samples.

B. A charitable pharmacy shall only possess and dispense prescription drug samples if the following conditions are satisfied:

1. the prescription drug samples are dispensed at no charge to qualified patients of that charitable pharmacy; and

2. the prescription drug samples are possessed in compliance with the Federal Prescription Drug Marketing Act of 1987, 21 U.S.C. §301 et seq., or its successor.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1307 (October 1997), LR 29:2099 (October 2003), effective January 1, 2004.

§2109. Medication Transfers

A. In facilities licensed by the Department of Health and Hospitals where United States Pharmacopeia (USP) storage requirements can be assured, prescription drugs, except controlled dangerous substances, dispensed in unit dose or in individually sealed doses may be transferred to a permitted charitable pharmacy for relabeling and dispensing to indigent patients, free of charge, pursuant to a valid prescription order.

1. The pharmacist-in-charge of the permitted charitable pharmacy shall be responsible for determination of suitability of the product for reuse.

a. No product where integrity cannot be assured shall be accepted for re-dispensing by the pharmacist.

b. A re-dispensed prescription medication shall be assigned the expiration date stated on the package.

c. No product shall be re-dispensed more than one time.

2. Pursuant to a voluntary agreement between the facility licensed by the Department of Health and Hospitals and a pharmacy holding a charitable pharmacy permit from the board, prescription drugs, except controlled dangerous substances, may be transferred from the facility to the pharmacy provided the following procedures are satisfied.

a. The physical transfer shall be accomplished by an individual authorized to do so by the charitable pharmacy.

b. The patient from whom the prescription medication was obtained shall document their consent for the donation; the consent shall be maintained on file at the facility.

c. The patient's name, prescription number, and any other identifying marks, shall be obliterated from the packaging prior to removal from the facility.

d. The drug name, strength, and expiration date shall remain on the medication package or label.

e. An inventory list of the drugs shall accompany the drugs being transferred. The list shall contain, at a minimum, the medication name, strength, quantity, and expiration date.

f. Expired drugs shall not be transferred. In the event expired drugs are received by a charitable pharmacy, the pharmacist-in-charge shall destroy them as required by law.

B. Under no circumstances may these transferred medications be re-distributed to another location.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2099 (October 2003), effective January 1, 2004.

§2111. Prohibitions

A. A charitable pharmacy shall not purchase, possess, trade, distribute, or dispense controlled dangerous substances.

B. A charitable pharmacy shall not be operated, or in any way associated, with any for-profit pharmacy permitted in this state or any other jurisdiction.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2099 (October 2003), effective January 1, 2004.

Chapter 23. Out-of-State Pharmacy

§2301. Purpose

A. Out-of-state pharmacies shall comply with the provisions of this Chapter in order to be and remain permitted to operate in Louisiana as an out-of-state pharmacy.

B. This Chapter applies to any place physically located outside the state of Louisiana that provides services in the state of Louisiana where prescription drugs are dispensed and/or pharmacy care is provided to residents of the state of Louisiana. This includes, but is not limited to, pharmacies providing goods and services via U.S. mail carrier, commercial carrier, the Internet, and/or directly to Louisiana residents.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1380 (December 1992), effective January 1, 1993, LR 29:2099 (October 2003), effective January 1, 2004.

§2303. Out-of-State Pharmacy Requirements

A. The out-of-state pharmacy shall hold a current pharmacy permit in good standing in the state(s) in which it is located and/or practicing pharmacy.

B. Each pharmacist dispensing drugs into Louisiana shall be licensed as a pharmacist in good standing in the state(s) where he practices.

C. Every out-of-state pharmacy doing business in Louisiana by dispensing and delivering prescription drugs and devices to Louisiana residents shall designate a resident agent and a registered office in Louisiana for the service of process.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1380 (December 1992), effective January 1, 1993, LR 29:2100 (October 2003), effective January 1, 2004.

§2305. Out-of-State Pharmacy Permit Requirements

A. The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board. The board may require such information as reasonably necessary to carry out the provisions of R.S. 37:1232, including, without limitation, the name, address, and position of each officer and director of a corporation or of the owners, if the pharmacy is not a corporation.

B. The out-of-state pharmacy shall pay an annual permit fee as defined in R.S. 37:1184.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1380 (December 1992), effective January 1, 1993, LR 29:2100 (October 2003), effective January 1, 2004.

§2307. Pharmacist-in-Charge

A. Designation. A pharmacist licensed by the Louisiana Board of Pharmacy shall be named in the application as the pharmacy's pharmacist-in-charge for the Louisiana permit and shall be responsible for the pharmacy permit's compliance.

B. The pharmacist-in-charge shall have an active and current license in the state in which he is practicing, and further, shall not have any restrictions that prohibit the position of pharmacist-in-charge.

C. Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

D. Policy and Procedure Manual. The pharmacist-in-charge shall be responsible for the development and maintenance of policies regarding quality pharmacy services including drug control, distribution, patient compliance accountability, inspection, and record keeping.

E. Circumvention. It is a violation of the pharmacy permit for any person to subvert the authority of the pharmacist-in-charge by impeding the management of the prescription department in the compliance of federal and state pharmacy laws and regulations.

F. Records. The pharmacist-in-charge is responsible for the proper maintenance of all prescription records. This necessarily includes electronic prescription records and the system's compliance and capacity to produce the required records.

G. Recall. The pharmacist-in-charge shall be responsible for the implementation of a recall procedure that can be readily activated to assure patient safety.

H. Discontinued or Outdated Drugs. The pharmacist-in-charge shall be responsible for the implementation of policies and procedures to ensure that discontinued drugs, outdated drugs, or drug containers with worn, illegible, or missing labels are withdrawn from the pharmacy inventory.

I. Change of Pharmacist-in-Charge. Written notice to the board shall be required when the pharmacist-in-charge designation for a pharmacy has changed.

1. The permit holder shall notify the board within 10 days of the prior pharmacist-in-charge's departure date. The permit holder shall designate a new pharmacist-in-charge within 10 days of the departure of the prior pharmacist-in-charge.

2. The new pharmacist-in-charge shall afford the board written notice of his newly designated pharmacist-in-charge status within 10 days of the departure of the prior pharmacist-in-charge.

3. A pharmacist-in-charge who voluntarily leaves a pharmacy shall give written notice to the board and the owner of the permit at least 10 days prior to this voluntary departure, unless replaced in a shorter period of time.

J. Affidavit of Responsibility and Duties. The designated pharmacist-in-charge shall sign an affidavit on a form supplied by the board indicating his understanding and acceptance of the duties and responsibilities of a pharmacist-in-charge. This notarized document shall be submitted to the board for inclusion in the pharmacy's record in the board office.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992), effective January 1, 1993, LR 29:2100 (October 2003), effective January 1, 2004.

§2309. Applicable Laws and Regulations

A. Louisiana pharmacy laws and regulations shall be applicable to regulate the practice of pharmacy for that portion of the out-of-state pharmacy's Louisiana pharmacy practice or operation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992), effective January 1, 1993, LR 29:2100 (October 2003), effective January 1, 2004.

§2311. Inspection

A. The facilities and records of the out-of-state pharmacy shall be subject to inspection by the board or its designated agent(s).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992), effective January 1, 1993, LR 29:2101 (October 2003), effective January 1, 2004.

§2313. Records

A. Records shall be maintained for not less than two years.

B. The pharmacy shall maintain records of drugs dispensed to Louisiana residents in such a manner so as to be identifiable, readily retrievable, and available upon request. Said records shall be made available for inspection by the board. The pharmacy permit holder or the pharmacist-in-charge shall produce within 72 hours any information, documentation, and/or records requested by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992), effective January 1, 1993, LR 29:2101 (October 2003), effective January 1, 2004.

§2315. Counseling Services

A. The pharmacy shall maintain an incoming toll-free telephone number for use by Louisiana consumers during regular office hours. Readily available telephone counseling services shall be provided that are consistent with the reasonable standard of due care. This telephone number, plus other numbers available for use, shall be printed on each container of drugs dispensed to Louisiana residents. The toll-free telephone number shall have sufficient extensions to provide reasonable access to incoming callers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992), effective January 1, 1993, LR 29:2101 (October 2003), effective January 1, 2004.

§2317. Out-of-State Pharmacy Closure Procedures

A. Notice. Notice shall be afforded the board not less than 10 days prior to the anticipated closure date of an out-of-state pharmacy. Said notice shall include the location of all transferred prescription files for Louisiana residents.

B. Permit. The out-of-state pharmacy permit holder shall surrender the pharmacy permit to the board upon closure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992), effective January 1, 1993, LR 29:2101 (October 2003), effective January 1, 2004.

§2319. Jurisdiction

A. Out-of-state pharmacies soliciting, receiving, and dispensing and delivering prescription drugs and devices, including controlled dangerous substances as defined in 21 U.S.C. 1 et seq., and 21 CFR 1 et seq., or their successors, and delivered to residents in Louisiana constitutes doing business in Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992), effective January 1, 1993, LR 29:2101 (October 2003), effective January 1, 2004.

Chapter 25. Prescriptions, Drugs, and Devices

Subchapter A. General Requirements

§2501. Prescription Drugs and Devices

A. Prescription Drugs or Devices. A prescription drug or device is a medication or mechanism that may only be dispensed by a pharmacist on the order of a licensed practitioner and shall bear the "Rx Only" notation or any other designation of similar import required by law on the label of a commercial container.

1. Dispensing. Prescription drugs or devices shall be dispensed only by a Louisiana-licensed pharmacist.

2. Possession. Prescription drugs or devices shall be procured and possessed in the course of the practice of pharmacy by a permitted pharmacy.

3. Storage. Prescription drugs or devices shall be stored in a permitted pharmacy under the immediate control and responsibility of a pharmacist.

B. Misbranded Drugs

1. Misbranded drugs are:

a. those drugs whose labeling is false or misleading in any particular manner; or

b. those drugs whose label does not bear the name and address of the manufacturer, packer, or distributor, and does not have an accurate statement of the quantities of the active ingredients; or

c. those drugs without an accurate monograph; or

d. those drugs meeting the qualifications for misbranded drugs as noted in the Federal Food, Drug, and Cosmetic Act, or its successor.

2. It is unlawful to possess or dispense misbranded drugs.

C. Adulterated Drugs

1. Adulterated drugs are contaminated medicinal substances having deleterious foreign or injurious materials, which fail to meet safety, quality, and/or purity standards.

2. It is unlawful to possess or dispense adulterated drugs.

D. Expired Drugs. Expired drugs shall not be dispensed and shall be removed from the pharmacy drug inventory.

E. Recalled Drugs. Recalled drugs shall be removed from the pharmacy inventory immediately upon notice. Recalls are classified as:

1. Class I—a situation in which there is a strong likelihood that the use of, or exposure to, a violative product will cause serious adverse health consequences or death;

2. Class II—a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote;

3. Class III—a situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2101 (October 2003), effective January 1, 2004.

§2503. Drug Returns

A. Drugs dispensed on prescription to a patient shall not be accepted for return, exchange, or re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2101 (October 2003), effective January 1, 2004.

§2505. Investigational Drugs

A. All investigational drugs stored or dispensed by any pharmacy shall conform to appropriate and applicable federal and state laws and regulations pertaining to their use.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2101 (October 2003), effective January 1, 2004.

§2507. Veterinary Prescription Drugs

A. Veterinary prescription drugs are prescription medications for animal use prescribed by a licensed veterinarian pursuant to a valid veterinarian-client-patient relationship and dispensed by a licensed pharmacist to the veterinarian's client, for a legitimate medical purpose, that are unsafe for unsupervised use as defined in 21 CFR §201.105, or its successor.

B. Dispensing Requirements. Veterinary prescription drugs shall be exclusively dispensed by a duly licensed pharmacist upon the order of a licensed veterinarian, unless otherwise provided by law.

C. Labeling Requirements. Veterinary prescription drugs shall be dispensed in an appropriate container, and in addition to the labeling requirements in Chapter 11 of these regulations, shall contain the following information:

1. the commercial label inscription "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; and

2. the client's name and patient's animal species.

D. Prescription Form Requirements. Prescriptions issued by a licensed veterinarian shall conform to §2511 of these regulations.

E. Storage. Veterinary prescription drugs shall be maintained in the prescription department of a pharmacy, and shall be kept separate and apart from drugs intended for human use.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2107 (October 2003), effective January 1, 2004.

§2509. Prescription Devices

A. In the interest of public health, safety, and welfare, the board may, from time to time, restrict the sale of certain devices to be dispensed only by a licensed pharmacist after a legitimate medical need has been demonstrated. A legitimate medical need includes the prevention of the transmission of communicable diseases.

B. Pharmacy Device. A pharmacy device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component or accessory, which is required under federal law to bear the label "Caution: Federal or State law requires dispensing by or on the order of a physician," and/or "Rx Only", or other designation of similar import.

1. Hypodermic Apparatus. Hypodermic means any syringe, needle, instrument, device, or implement intended or capable of being adopted for the purpose of administering drugs by subcutaneous, intramuscular, or intravenous injection.

a. Sale. Hypodermic syringes and/or needles shall be sold or distributed only by a licensed pharmacist, physician, dentist, veterinarian, podiatrist, embalmer, drug wholesaler, surgical supplier, or other legally authorized distributor.

b. Storage. Hypodermic syringes and/or needles shall be stored in the prescription department or in another secure area.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2107 (October 2003), effective January 1, 2004.

Subchapter B. Prescriptions

§2511. Prescriptions

A. Definitions. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section.

Electronic Prescription—a prescription transmitted in electronic form.

Practice Affiliation—a practice relationship, collaboration, or practice under the supervision of a physician licensed to practice medicine.

Prescription or Prescription Drug Order—an order from a practitioner authorized by law to prescribe for a drug or device that is patient specific and is communicated by any means to a pharmacist in a permitted pharmacy, and is to be preserved on file as required by law or regulation.

B. Written Prescriptions. A written prescription shall conform to the following format.

1. The prescription form shall not be less than 4 inches by 5 inches, and shall bear a single printed signature line.

2. The prescription form shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and, if applicable, Drug Enforcement Administration (DEA) registration number. In the event that multiple practitioners are identified on the prescription form, the authorizing prescriber's specific identity shall be clear and unambiguous. This identification may be indicated by any means, including but not limited to, a marked check box next to, or circling the authorizing prescriber's printed name.

3. If the authorized prescriber is a non-physician, the prescription form shall clearly indicate the authorized prescriber's practice affiliation. The affiliated physician's name, address, and telephone number shall appear on the prescription form.

4. No prescription form shall contain more than four prescription drug orders. Each prescription drug order on the form shall provide the following:

a. check box labeled "Dispense as Written", or "DAW", or both; and

b. the number of refills, if any.

5. Forms used by pharmacists to record telephoned or transferred prescriptions are exempt from the format requirements listed above.

6. Equivalent Drug Product Interchange

a. The pharmacist shall not select an equivalent drug product when the prescriber handwrites a mark in the check box labeled "Dispense as Written", or "DAW", or both, and personally handwrites his signature on a printed single signature line. Otherwise, the pharmacist may select an equivalent drug product, provided the patient has been informed of, and has consented to, the proposed cost saving interchange.

b. In the event an authorized prescriber has indicated that an equivalent drug product interchange is prohibited by handwriting a mark in the check box labeled "Dispense as Written", or "DAW", or both, then a non-licensed, non-certified, or non-registered agent of the pharmacy shall not inquire as to a patient's desire for an equivalent drug product interchange.

c. For prescriptions reimbursable by Medicaid or Medicare, the authorized prescriber may only prohibit equivalent drug product interchange by handwriting the words "brand necessary" or "brand medically necessary" on the face of the prescription order or on a sheet attached to the prescription order.

C. Oral Prescriptions

1. Upon the receipt of an oral prescription from an authorized prescriber, the pharmacist shall reduce the order to a written form prior to dispensing the medication.

2. The pharmacist shall not select an equivalent drug product when the authorized prescriber or his agent has verbally indicated a specific brand name drug or product is ordered.

3. The pharmacist may select an equivalent drug product if the authorized prescriber or his agent has given his approval to the equivalent drug product interchange. The patient shall be informed of, and consent to, the proposed cost saving interchange.

D. Electronic Prescriptions

1. The prescription shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number and, if applicable, DEA registration number.

2. If the authorized prescriber is a non-physician, the prescription form shall clearly indicate the authorized prescriber's practice affiliation. The affiliated physician's name, address, and telephone number shall appear on the prescription form.

3. The pharmacist shall not select an equivalent drug product when the prescriber indicates in the check box labeled "Dispense as Written", or "DAW", or both, and electronically transmits his signature on the formatted single signature line. Otherwise, the pharmacist may select an equivalent drug product, provided the patient has been informed of, and consents to, the proposed cost saving interchange.

4. Facsimile Prescription

a. The receiving facsimile machine of a prescription transmitted by facsimile shall be located within the pharmacy department.

b. The prescription transmitted by facsimile shall be on a non-fading legible medium.

c. All requirements applicable to written prescriptions in Subsection B shall apply to facsimile prescriptions, except Subparagraph B.6.c.

E. Exclusion. The provisions of this Section shall not apply to medical orders written for patients in facilities licensed by the Department of Health and Hospitals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2102 (October 2003), effective January 1, 2004.

§2513. Prescription Receipt and Verification

A. Receipt of a Prescription

1. Written. A pharmacist may receive and dispense a prescription that has been written and/or signed by the practitioner.

2. Oral. A pharmacist may receive and dispense a prescription that has been orally communicated by the practitioner when the prescription has been reduced to hard copy.

3. Electronic Transmission. A pharmacist may receive a prescription via electronic or other means, and then reduce to hard copy, if necessary.

B. Verification. Verification of the accuracy and authenticity of any prescription is the responsibility of the pharmacist.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2103 (October 2003), effective January 1, 2004.

§2515. Prescriptions Based upon Electronic Questionnaires

A. A prescription issued solely on the results of answers to an electronic questionnaire, in the absence of a documented patient evaluation including a physical examination, is issued outside the context of a valid physician-patient relationship, and is not a valid prescription.

B. If a pharmacist has reasons to suspect that a prescription was authorized solely on the results of an electronic questionnaire and in the absence of a documented patient evaluation including a physical examination, the pharmacist shall ascertain if that practitioner's standard of practice allows that practitioner to authorize a prescription under such circumstances. Reasons to suspect that a prescription may have been authorized in the absence of a valid physician-patient relationship, or in violation of the practitioner's standard of practice, include:

1. the number of prescriptions authorized on a daily basis by the practitioner;

2. the manner in which the prescriptions are authorized by the practitioner or received by the pharmacy, i.e., electronically;

3. the geographical distance between the practitioner and the patient(s);

4. knowledge by the pharmacist that the prescription was issued solely as a result of answers to an electronic questionnaire; or

5. knowledge by the pharmacist that the pharmacy he works for directly or indirectly participates in an internet site that markets prescription drugs to the public.

C. A pharmacist who has reasons to suspect that a prescription may have been authorized in the absence of a valid physician-patient relationship, or otherwise in violation of the prescriber's standard of practice, shall not fill such prescription until he has obtained proof to a reasonable certainty of the validity of such prescription.

D. A pharmacist who dispenses prescription drugs in violation of this Section is not acting in the best interest of the patient and is dispensing outside the course of the professional practice of pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2103 (October 2003), effective January 1, 2004.

§2517. Prescription Dispensing

A. Prescription dispensing means the issuance, by a licensed pharmacist, of one or more doses of medication in a suitable container, properly labeled for subsequent administration, and shall consist of the following procedures or practices:

1. receiving and interpretation of the prescription order;

2. assembling the drug products and an appropriate container;

3. preparing the prescription by compounding, mixing, counting, or pouring;

4. affixing the proper label to the final container;

5. patient counseling as required; and

6. transfer of possession.

B. Unless otherwise allowed by law, drugs dispensed on prescription to a patient shall not be accepted for return, exchange, or re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004.

§2519. Prescription Refills

A. Refill Authorization. Prescription refills may be dispensed only with the prescriber's authorization, as indicated on the original prescription order. In the absence of the authorized practitioner's instructions on the original prescription, the prescription shall be considered non-refillable. When all refills authorized on the original prescription have been dispensed, then authorization from the prescribing practitioner shall be obtained prior to dispensing.

B. Controlled Dangerous Substances

1. The refilling of a prescription for a drug listed in Schedule II is prohibited.

2. A prescription for a drug listed in Schedule III, IV, or V may be refilled up to five times, if so indicated at the time issued.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004.

§2521. Emergency Refills

A. Using sound professional judgment, a pharmacist may refill adequate medication for a 72-hour regimen when an emergency for medication has been adequately demonstrated and the prescribing practitioner is not available.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004.

§2523. Transfer of Prescription Information

A. The transfer of original and subsequent prescription information, for the purpose of refill dispensing, is permissible between pharmacies, subject to the following requirements and/or limitations.

1. The transfer of original prescription information for controlled dangerous substances listed in Schedules III, IV, or V between pharmacies is permissible on a one-time basis.

2. The transfer of prescription information for drugs not listed on Schedules II, III, IV, or V is permissible between pharmacies.

B. The required electronic record keeping system shall have a mechanism to prohibit the transfer of prescriptions for controlled dangerous substances that have been previously transferred, unless the pharmacy can electronically access the prescription drug records at the pharmacy from which the transfer is requested.

C. The original prescription that has been transferred shall be invalidated in the system for purposes of refilling, unless other pharmacies may electronically access the prescription drug records for purposes of transfer. All required information shall be maintained for a minimum of two years.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004.

§2525. Prescription Expiration

A. A prescription for a drug other than a controlled dangerous substance shall expire one year after the date written.

B. A prescription for a controlled dangerous substance listed in Schedule II, III, IV, or V shall expire six months after the date written.

C. Expired prescriptions shall not be refillable or renewable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004.

§2527. Prescription Labeling

A. An appropriate label shall be affixed to a proper container, and shall bear the following minimum information:

1. pharmacy's name, address, and telephone number;
2. prescription number;
3. authorized prescriber's name;
4. patient's name;
5. date dispensed;
6. drug name and strength;
7. directions for use, as indicated;
8. pharmacist's name or initials; and
9. cautionary auxiliary labels, if applicable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004.

§2529. Pharmacy Prepackaging

A. *Prepackaging* is the preparation of medication in a unit-of-use container by a pharmacist in a pharmacy prior to the receipt of a prescription for ultimate prescription dispensing by a pharmacist in Louisiana.

B. Labeling. The label on the prepackaged container shall contain the following minimum information:

1. drug name;
2. dosage form;
3. strength;
4. quantity;

5. name of manufacturer and/or distributor;

6. manufacturer's lot or batch number;

7. date of preparation;

8. pharmacist's initials; and

9. expiration date according to United States Pharmacopeia (USP) guidelines.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004.

Subchapter C. Compounding of Drugs

§2531. Purpose and Scope

A. Purpose. The rules of this Subchapter describe the requirements of minimum current good compounding practices for the preparation of drug products by Louisiana-licensed pharmacists for dispensing and/or administration to patients.

B. Scope. These requirements are intended to apply to all compounded products, sterile and non-sterile, regardless of the location of the patient, e.g., home, hospital, nursing home, hospice, or physician's office.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004.

§2533. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section.

Biological Safety Cabinet—a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49, or its successor.

Class 100 Environment—an atmospheric environment that contains fewer than 100 particles, of the size 0.5 microns or less in diameter, per cubic foot of air, according to Federal Standard 209E, or its successor.

Component—an ingredient used in the *compounding* of a drug product.

Compounding—the preparation, mixing, assembling, packaging, or labeling of a drug or device by a pharmacist for his patient as the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice, or including the preparation of drugs or devices in anticipation of prescription orders to be received by the *compounding* pharmacist based on routine, regularly observed prescribing patterns. *Compounding* does not include the *compounding* of drug products that are essentially copies of a commercially available product.

Cytotoxic—any pharmaceutical that has the capability of killing living cells.

Practitioner Administered Compounds—products compounded by a licensed pharmacist, upon the medical order of a licensed prescriber for administration by a prescriber for diagnostic or therapeutic purposes.

Sterile Compounding—*compounding* performed using established aseptic technique and utilizing a laminar air flow hood or other device capable of providing a *sterile compounding* environment. *Sterile compounding* shall be used when *compounding* parenteral medications or products, ophthalmic preparations, or any other preparation requiring sterile techniques.

Sterile Product—any dosage form devoid of viable microorganisms including, but not limited to, parenterals, injectables, and ophthalmics.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004.

§2535. General Standards

A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the-counter medications, chemicals, compounds, or other components.

1. A pharmacy shall have written procedures as necessary for the compounding of drug products to assure that the finished products have the identity, strength, quality, and purity they are represented to possess.

2. All compounding shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment.

3. Products or duplicates of products removed from the market for the purposes of safety shall not be used to compound prescriptions for human use.

B. Beyond Use Date. Compounded medications shall be labeled with a beyond use date of no more than 180 days, unless documentation on file supports a longer beyond use date.

C. Records and Reports. Any procedures or other records required to comply with this Section shall be maintained for a minimum of two years.

D. Compounding for Prescriber's Use. Pharmacists may prepare practitioner administered compounds for a prescriber's use with the following requirements:

1. an order by the prescriber indicating the formula and quantity ordered to be compounded by the pharmacist;

2. the product is to be administered by the prescriber and not dispensed to the patient; and

3. the pharmacist shall generate a label and sequential identification number for the compounded drug.

E. Anticipated Use Products. The pharmacist shall label any excess compounded product so as to reference it to the formula used and the assigned lot number and estimated beyond use date based on the pharmacist's professional judgment and/or other appropriate testing or published data.

F. Labeling of Compounded Products

1. For patient-specific compounded products, the labeling requirements of R.S. 37:1225, or its successor, as well as this Chapter, shall apply.

2. All practitioner administered compounds shall be packaged in a suitable container with a label containing, at a minimum, the following information:

a. pharmacy's name, address, and telephone number;

b. practitioner's name;

c. name of preparation;

d. strength and concentration;

e. lot number;

f. beyond use date;

g. special storage requirements, if applicable;

h. assigned identification number; and

i. pharmacist's name or initials.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1316 (October 1997), LR 29:2105 (October 2003), effective January 1, 2004.

§2537. Requirements for Compounding of Sterile Products

A. Board Notification. An applicant or pharmacy permit holder who wishes to engage in the practice of sterile product compounding shall notify the board prior to beginning that practice, and shall receive approval from the board.

B. Personnel

1. The pharmacist-in-charge shall be responsible for the following:

a. procurement, storage, compounding, labeling, dispensing, and distribution of all prescription drugs, devices, and related materials necessary in compounding and dispensing sterile products;

b. establishment of policies and procedures for the compounding and dispensing of sterile products. The policy and procedure manual shall be current, accessible to all staff, and available for inspection by the board upon request. The policy and procedure manual shall, at a minimum, include:

i. policies and procedures for the compounding and dispensing of sterile products;

ii. a quality assurance program for the purpose of monitoring patient care, adverse drug reactions, personnel qualifications, training and performance, product integrity, equipment, record keeping, facilities, infection control;

iii. guidelines regarding patient education; and

iv. procedures for the handling and disposal of cytotoxic agents, waste, and spills;

c. documentation of competency in aseptic techniques. The aseptic technique of each individual compounding and dispensing sterile products shall be observed and evaluated as satisfactory during orientation and training, and at least on an annual basis thereafter.

2. Training and Education. All individuals compounding and preparing sterile products shall:

a. obtain practical and/or academic training in the compounding and dispensing of sterile products;

b. complete a minimum of one hour of American Council on Pharmaceutical Education (ACPE) or board-approved continuing education, on an annual basis, related to sterile product compounding, dispensing, and utilization;

c. use proper aseptic technique in all sterile product compounding as defined by the pharmacy practice site's policy and procedure manual;

d. qualify through an appropriate combination of specific training and experience to operate or manipulate any item of equipment, apparatus, or device to which such persons will be assigned to use to compound and dispense sterile products; and

e. maintain in the pharmacy practice site a written record of initial and subsequent training and competency evaluations. The record shall contain the following minimum information:

i. name of the individual receiving the training/evaluation;

ii. date of the training/evaluation;

iii. general description of the topics covered;

iv. signature of the individual receiving the training/evaluation; and

v. name and signature of the individual providing the training/evaluation.

C. Physical Requirements

1. The pharmacy shall have a designated area with entry restricted to designated personnel for preparing sterile products, and the designated area shall be:

a. structurally isolated from other areas with restricted entry or access and shall be configured in such a manner so as to avoid unnecessary traffic and airflow disturbances from activity within the controlled facility;

b. used only for the preparation of these sterile products; and

c. sufficient in size to accommodate a laminar air flow hood or other device capable of providing a sterile compounding environment and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

2. The pharmacy where sterile products are prepared shall have:

a. a sink with hot and cold running water that shall be located in, or adjacent to, the area where sterile products are compounded;

b. appropriate environmental control devices capable of maintaining at least Class 100 environment in the workplace where critical objects are exposed and critical operations are performed. These devices, e.g., laminar air flow hoods, and other zonal laminar flow hoods utilizing High Efficiency Particulate Air (HEPA) filters, shall be capable of maintaining Class 100 conditions during normal activity;

c. appropriate refrigeration for storing supplies and sterile products requiring refrigeration subsequent to their preparation and prior to their dispensing or administration to patients. The pharmacy shall maintain documentation of refrigeration integrity, in accordance with its policies and procedures;

d. appropriate disposal containers for used needles, syringes, and other sharps, and if applicable, for cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patients' homes; and

e. temperature-controlled delivery containers, when required.

3. The pharmacy shall maintain supplies adequate to ensure an environment suitable for the aseptic preparation of sterile products. Within the sterile compounding area, prescription drugs, devices, and related materials shall not be stored in shipping containers constructed of corrugated cardboard or other high particulate-producing materials.

4. The pharmacy shall maintain current reference materials related to sterile products accessible to all personnel.

D. Drug Handling. Any sterile compounded product shall be shipped or delivered to a patient in appropriate temperature-controlled delivery containers as defined by USP standards and appropriately stored.

E. Cytotoxic Drugs. In addition to the minimum standards for a pharmacy established by the board, the following requirements are established for pharmacies that prepare cytotoxic drugs, to insure the protection of the personnel involved.

1. All cytotoxic drugs shall be compounded in a vertical flow, Class II Biological Safety Cabinet. Other products shall not be compounded in this cabinet.

2. Personnel compounding cytotoxic drugs shall wear protective apparel, including disposable masks, gloves, and gowns with tight cuffs.

3. Personnel compounding cytotoxic drugs shall use appropriate safety and containment techniques.

4. Prepared doses of cytotoxic drugs shall:

a. be dispensed and labeled with proper precautions on the inner and outer containers or other device capable of providing a sterile environment; and

b. be shipped in a manner to minimize the risk of accidental rupture of the primary container.

5. Disposal of cytotoxic waste shall comply with all applicable federal, state, and local requirements.

6. A "Chemo Spill Kit" shall be readily available in the work area, and shall consist of appropriate materials needed to clean up spills of hazardous drugs. Personnel shall be trained in its appropriate use for handling both minor and major spills of cytotoxic agents.

F. Quality Control

1. An ongoing quality control program shall be maintained and documented that monitors personnel performance, equipment, and facilities. Appropriate samples of finished products shall be examined to assure that the pharmacy is capable of consistently preparing sterile products meeting specifications.

a. All clean rooms and laminar flow hoods shall be certified by an independent contractor according to federal standards for operational efficiency at least every six months. Appropriate certification records shall be maintained.

b. Written procedures shall be developed requiring sampling if/when microbial contamination is suspected.

c. When bulk compounding of sterile solutions is performed using non-sterile chemicals, extensive end-product testing shall be documented prior to the release of the product from quarantine. This process shall include appropriate tests for particulate matter and testing for pyrogens.

d. Written justification shall be maintained of the chosen "beyond use" dates for compounded products.

e. Documentation shall be maintained of quality control audits at regular, planned intervals, including infection control and sterile technique audits.

G. Labeling

1. All practitioner administered sterile compounds shall be packaged in a suitable container, and shall bear a label with the following minimum information:

a. pharmacy's name, address, and telephone number;

b. preparation name;

c. strength and concentration;

d. lot number;

e. beyond use date;

f. practitioner's name;

g. assigned identification number;

h. special storage requirements, if applicable; and

i. pharmacist's name or initials.

2. The labeling for all other sterile compounds shall be in accordance with the prescription labeling requirements in §2537 of this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2106 (October 2003), effective January 1, 2004.

Subchapter D. Controlled Dangerous Substances

§2539. Controlled Dangerous Substances (CDS),

A. Purpose. The purpose of this Section is to prevent the diversion of controlled dangerous substances by prohibiting the manufacturing, distributing, dispensing, or administering of controlled dangerous substances not in the usual course of professional practice.

B. Classification. Controlled dangerous substances are specifically identified by reference, as provided in R.S. 40:961 et seq., or its successor, and 21 CFR §1308 et seq., or its successor. Schedules I, II, III, IV, and V shall, unless and until added to pursuant to R.S. 40:961 et seq., or its successor, consist of the drugs or other substances, by whatever official name, common or usual name, chemical name, or trade name designated, listed in R.S. 40:961 et seq., or its successor.

C. Definition and Composition. Controlled dangerous substances are categorized into various schedules based upon the degrees of potential for abuse, as follows:

1. Schedule I:

a. the drug or other substance has a high potential for abuse;

b. the drug or other substance has no currently accepted medical use in treatment in the United States; and

c. there is a lack of accepted safety for use of the drug or other substance under medical supervision.

2. Schedule II:

a. the drug or other substance has a high potential for abuse;

b. the drug or other substance has a currently accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions; and

c. abuse of the drug or other substance may lead to severe psychological or physical dependence.

3. Schedule III:

a. the drug or other substance has a potential for abuse less than the drugs or other substances listed in Schedules I and II;

b. the drug or other substance has a currently accepted medical use in treatment in the United States; and

c. abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

4. Schedule IV:

a. the drug or other substance has a low potential for abuse relative to the drugs or other substances listed in Schedule III;

b. the drug or other substance has a currently accepted medical use in treatment in the United States; and

c. abuse of the drug or other substance may lead to limited psychological or physical dependence relative to the drugs or other substances listed in Schedule III.

5. Schedule V:

a. the drug or other substance has a low potential for abuse relative to the drugs or other substances listed in Schedule IV;

b. the drug or other substance has a currently accepted medical use in treatment in the United States; and

c. abuse of the drug or other substance may lead to limited psychological or physical dependence relative to the drugs or other substances listed in Schedule IV.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2107 (October 2003), effective January 1, 2004.

§2541. CDS License Requirements

A. A pharmacy shall apply to the board in order to receive a license to dispense controlled dangerous substances.

1. Initial Application. The Louisiana Board of Pharmacy Controlled Dangerous Substance license shall be applied for by an applicant on the board application form and approved by the board prior to opening any pharmacy having controlled dangerous substances.

2. Renewal. The CDS license shall be renewed annually. A CDS license that has not been renewed by December 31 of each year shall expire and be null and void.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2108 (October 2003), effective January 1, 2004.

§2543. CDS Prescription/Order Requirements

A. Controlled Dangerous Substance Prescription Form

1. Prescriptions for controlled dangerous substances shall be written or reduced to writing with ink, indelible pencil, printed, or electronically generated, and shall bear the following minimum information:

a. patient information:

i. full name; and

ii. address and telephone number;

b. practitioner information:

i. full name;

ii. address and telephone number;

iii. Drug Enforcement Administration (DEA) registration number; and

iv. original handwritten signature for drugs listed in Schedule II;

c. drug information:

i. name;

ii. dosage form;

iii. strength;

iv. quantity prescribed; and

v. directions for use.

2. All prescriptions for controlled dangerous substances shall be dated as of, and signed on, the day when issued.

B. Prescriptions for Drugs Listed in Schedule II

1. Prescriptions for drugs listed in Schedule II shall be signed by an authorized practitioner.

2. Prescriptions for drugs listed in Schedule II shall not be filled beyond six months after the date of issue.

3. Authorization for Emergency Dispensing. A pharmacist may dispense a prescription for a drug listed in Schedule II in the case of an emergency situation upon a prescribing practitioner's verbal authorization within the following limitations.

a. Emergency. An emergency situation exists when:

i. administration is necessary for immediate treatment;

ii. an appropriate alternate treatment is not available; and

iii. the prescribing practitioner cannot reasonably provide a written prescription.

b. Adequate Regimen. The pharmacist shall dispense a limited amount of the drug required to treat the patient during the emergency period.

c. Reduced to Writing. An oral prescription in an emergency situation shall be immediately reduced to writing, in proper form, with the required information, by the dispensing pharmacist with the dispensing pharmacist's signature.

d. Verification. A pharmacist shall verify the authenticity of an oral prescription for a drug listed in Schedule II. If the prescribing practitioner is not known to the pharmacist, he shall make a reasonable effort to determine that the oral authorization came from an authorized practitioner. Such efforts may include, but are not limited to, a callback to the prescribing practitioner, and/or other good faith efforts to insure the practitioner's authority is valid.

e. Prescription Retrieval. A written prescription for the drug listed in Schedule II, signed by the authorized practitioner, in proper form with the required information, shall be delivered to the dispensing pharmacist from the practitioner within seven days from the date the oral prescription was issued. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it shall be postmarked within the seven-day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription that had earlier been reduced to writing. The pharmacist shall notify the nearest office of the DEA if the prescribing practitioner fails to deliver a written prescription within the specified time frame.

4. Refills Prohibited. The refilling of a prescription for a drug listed in Schedule II is prohibited.

5. Prescriptions Received Via Facsimile. A practitioner or the practitioner's agent may transmit a prescription written for a drug listed in Schedule II to a pharmacy via facsimile equipment, provided that the original signed prescription is presented to the pharmacist for review prior to the actual dispensing of the prescription, unless one of the following exceptions applies.

a. A prescription written for a drug listed in Schedule II to be compounded for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the practitioner or practitioner's agent to the dispensing pharmacy by facsimile. The facsimile may serve as the original written prescription.

b. A prescription written for a drug listed in Schedule II for a resident of a long-term care facility may be transmitted by the practitioner or practitioner's agent to the dispensing pharmacy by facsimile. The facsimile may serve as the original written prescription.

c. A prescription written for a drug listed in Schedule II for a hospice or terminally ill patient may be transmitted by the practitioner or practitioner's agent to the dispensing pharmacy. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice or terminally ill patient. The facsimile may serve as the original written prescription.

6. Partial Filling. The partial filling of a prescription for a drug listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity prescribed in a written or emergency oral prescription and the pharmacist makes a notation of the quantity supplied on the face of the written prescription or written record of the oral emergency prescription.

a. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. However, if the remaining portion is not filled within the 72 hour period, the pharmacist shall notify the prescribing practitioner.

b. No further quantity may be supplied beyond 72 hours without a new prescription.

c. Partial Filling for Patient of Long-Term Care Facility or for Patient with Terminal Illness. A prescription for a drug listed in Schedule II for a patient in a long-term care facility or for a patient with a terminal illness may be filled in partial quantities.

i. For each partial filling, the dispensing pharmacist shall record on the prescription whether the patient resides in a long-term care facility or has a terminal illness, and then record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the following information:

(a). the date of the partial filling;

(b). quantity dispensed; and

(c). name or initials of the dispensing pharmacist.

ii. The remaining portion may be filled within 60 days of the first partial filling. However, if the remaining portion is not filled within the 60-day period, the pharmacist shall notify the prescribing practitioner.

iii. No further quantity may be supplied beyond the 60-day period without a new prescription.

7. Completion of Prescription. After consultation with the prescribing practitioner, and the appropriate documentation thereof, a pharmacist may complete, but not alter, a prescription.

a. A pharmacist may complete the following information on a prescription:

i. patient's address;

ii. drug strength;

iii. drug quantity; and/or

iv. directions for use.

b. A pharmacist may add the following information to a prescription:

i. patient's address;

ii. drug dosage form; and/or

iii. prescriber's DEA registration number.

c. A pharmacist shall not make changes to the following information on a prescription:

i. patient's name;

ii. date of issue;

iii. drug name, except for generic interchange as allowed by law; or

iv. practitioner signature.

C. Prescriptions for Drugs Listed in Schedules III, IV, or V. Prescriptions for drugs listed in Schedules III, IV, or V may be dispensed upon receipt of oral, written, or electronic prescriptions of an authorized practitioner.

1. Oral Prescriptions for Drugs Listed in Schedules III, IV, or V. Oral prescriptions shall be promptly reduced to writing with the required information.

2. Refilling of Prescriptions for Drugs Listed in Schedules III, IV, or V. Such prescriptions are refillable, with appropriate authorization.

3. Prescription Form for Drugs Listed in Schedules III, IV, or V. Such prescriptions shall conform to the following requirements.

a. Refill Authority. A practitioner shall orally approve or inscribe refill instructions on the face of the prescription. In the absence of specific refill instructions, the prescription is not refillable.

b. Refill Period. Such prescriptions shall not be refilled more than the number of times authorized by the prescribing practitioner, and in no case shall they be refilled more than five times within six months of the date of issue. Such prescriptions shall expire and become null and void six months after the date of issue, or after five authorized refills, whichever occurs first.

c. Partial Filling. Partial filling of such prescriptions is permissible, provided that:

i. each partial filling is recorded in the same manner as a refill;

ii. the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and

iii. no dispensing shall occur after six months beyond the date of issue.

d. Refill Records. The dispensing pharmacist shall note in the required electronic record keeping system refill information, indicating the date, with quantity or variation of quantity dispensed, and pharmacist's name or initials.

D. Labeling of Dispensed Controlled Dangerous Substances. In addition to the labeling requirements enumerated in Chapter 11 of these regulations, a prescription label for a controlled dangerous substance shall include the federal transfer caution label.

E. CDS Prescription Files. Prescription files for controlled dangerous substances shall be maintained on the pharmacy premises.

1. Prescription Files for Drugs Listed in Schedule II. Such prescriptions shall be maintained separately from other prescriptions, and shall contain the name or initials of the dispensing pharmacist.

2. Prescription Files for Drugs Listed in Schedules III, IV, or V. Such prescriptions shall be maintained separately from other prescriptions, or in the alternative, may be filed in numerical sequence with either prescriptions for drugs listed in Schedule II, or all other prescriptions. The name, or initials, of the dispensing pharmacist, as well as the dispensing date, shall be placed on, or attached to, the prescription.

3. Prescription files for all controlled dangerous substances shall be maintained in readily available and retrievable manner.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2108 (October 2003), effective January 1, 2004.

§2545. CDS Dispensing

A. Controlled dangerous substances shall only be dispensed by a licensed pharmacist at a permitted pharmacy in the usual course of professional practice pursuant to a valid prescription or order. A valid prescription or order is a prescription or order issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice.

B. Professional Conduct. A license, registration, certification, permit, or any other designation deemed necessary to practice, or assist in the practice, of pharmacy may be subject to discipline when deviating from primary or corresponding responsibility to avert the following prohibited acts.

1. Primary Responsibility

a. Drug Diversion. Attempted, actual or conspired dispensing, distributing, administering, or manufacturing of a controlled dangerous substance not pursuant to a valid prescription or order while acting in the course of professional pharmacy practice is prohibited.

b. Possession. Actual or conspired possession of a controlled dangerous substance not pursuant to a valid prescription or order issued for a legitimate medical purpose by an authorized practitioner in the usual course of professional practice.

2. Corresponding Responsibility

a. Medical Purpose. The prescribing practitioner has the primary responsibility to issue a prescription for a controlled dangerous substance for a legitimate medical purpose, but a corresponding responsibility rests with the pharmacist dispensing said prescription to ascertain that said prescription was issued for a legitimate medical purpose in the usual course of professional practice.

b. Authenticity. A pharmacist shall exercise sound professional judgment to ascertain the validity of prescriptions for controlled dangerous substances. If, in the pharmacist's professional judgment, a prescription is not valid, that pharmacist shall not dispense said prescription.

3. Forged Prescriptions. It is unlawful for a pharmacist to forge a prescription, or to dispense a forged prescription, for a controlled dangerous substance. The pharmacist shall exercise professional diligence in determining the validity of a prescription as to the practitioner's authority and/or patient's identity, in order to prevent misrepresentation, fraud, deception, subterfuge, conspiracy, or diversion of controlled dangerous substances.

4. Altered Prescriptions. It is unlawful for a pharmacist to personally alter a prescription, or to dispense an altered prescription, for a controlled dangerous substance, except as provided by law or this Chapter.

C. Accountability. The pharmacist-in-charge, the registrant/permittee, and/or other designated responsible parties, shall be accountable for shortages of controlled dangerous substances or inconsistencies indicated in an audit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2110 (October 2003), effective January 1, 2004.

§2547. CDS Record Keeping

A. The permittee shall maintain readily retrievable, complete, and accurate transaction records, as follows:

1. DEA order forms;

2. receiving invoices such that invoices for drugs listed in Schedule II shall be maintained separately, but invoices for drugs listed in Schedules III, IV, and V may be maintained with general records provided they are readily retrievable;

3. prescription files; and

4. inventory records of all controlled dangerous substances, including the initial, annual, and current inventory.

B. Inventory Records. Such records shall be complete and reflect an accurate accounting of all transactions involving controlled dangerous substances.

1. Content. The record shall reflect the following information:

a. drug name, strength, and correct accounting supported with invoices, prescriptions, and/or transfers;

b. permittee name and address;

c. permittee's DEA registration number;

d. date of inventory, including whether taken at opening or close of business;

e. time period;

f. available prior inventory;

g. signature of pharmacist-in-charge; and

h. inventory records shall be maintained for two years.

2. Initial Inventory Record. An initial inventory of all controlled dangerous substances shall be conducted when the permittee commences to dispense prescriptions for controlled dangerous substances.

3. Annual Inventory Record

a. A complete and accurate physical inventory shall be conducted of all drugs listed in Schedule II.

b. An estimated physical inventory shall be conducted of all drugs listed in Schedules III, IV, and V, unless the container holds more than 1,000 tablets or capsules, in which case an exact inventory shall be made.

c. The annual inventory may be taken on any date that is within one year of the previous inventory date.

4. Business Termination Inventory. An inventory of all controlled dangerous substances shall be taken when a permittee's pharmacy is sold, exchanged, assigned, closed, or transferred, with a copy of said inventory mailed to the board and the DEA.

5. Pharmacist-in-Charge Termination Inventory. An inventory of all controlled dangerous substances shall be conducted by the departing pharmacist-in-charge and verified by the succeeding pharmacist-in-charge.

6. Central Records. A central records depository shall be permitted, if approved by both the DEA and the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2110 (October 2003), effective January 1, 2004.

§2549. CDS Theft or Loss

A. The unexplained substantial loss, disappearance, or theft of controlled dangerous substances from a pharmacy shall be documented by the permittee.

1. Inventory. The permittee shall conduct a physical inventory of all controlled dangerous substances.

2. Report. The permittee shall substantiate the loss or theft of controlled dangerous substances by completing the DEA Form 106—Report of Theft or Loss of Controlled Substances, or its successor.

3. Notice. The permittee shall file the above-referenced report to the DEA and to the board within 10 days of discovery of the theft or loss.

4. Drug Diversion. The permittee shall report diversion of controlled dangerous substances to the board within ten days of discovery of the diversion.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2111 (October 2003), effective January 1, 2004.

§2551. CDS Returns

A. A permittee is authorized to return drugs listed in Schedule II to a legally authorized supplier or reverse distributor, provided that an executed DEA 222 Form, or its successor, shall be completed by said supplier or reverse distributor and maintained by the permittee.

B. A permittee is authorized to return drugs listed in Schedules III, IV, or V to a legally authorized supplies or reverse distributor, provided that a written record is maintained, including the following information:

1. the date of the transaction;

2. the drug name, dosage form, strength, and quantity;

3. the name, address, and DEA registration number of the supplier or reverse distributor; and

4. the name, address, and DEA registration number of the permittee.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2111 (October 2003), effective January 1, 2004.

§2553. CDS Destruction

A. Destruction. Deteriorated, outdated, recalled, or nontransferable drugs shall be inventoried on DEA Form 41—Registrants Inventory of Drugs Surrendered, or its successor. The registrant shall forward three copies of the completed form to the regional DEA office and await DEA's instructions on proper procedures. A copy of the inventory sent to the regional DEA office shall be sent to the board.

B. Record Retention. The registrant shall maintain all applicable records for a minimum of two years.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2111 (October 2003), effective January 1, 2004.

§2555. Pharmacy Termination or Transfer

A. A permittee discontinuing dispensing of controlled dangerous substances shall notify the board and then remove the drugs, through return or transfer, to legally authorized recipients.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2111 (October 2003), effective January 1, 2004.

§2557. CDS Transfers

A. Transfer to Practitioner's Office. A permittee may distribute controlled dangerous substances to a DEA-registered practitioner for the purpose of administering said drug for office use, provided that the following conditions are met.

1. The transfer of drugs listed in Schedule II to a DEA-registered practitioner for office use shall require the completion of a DEA Form 222, or its successor.

2. The transfer of drugs listed in Schedules III, IV, or V to a DEA-registered practitioner for office use shall require a written order, or an oral order reduced to written form, and the order shall be maintained with the receiving invoices for said drugs.

B. Transfer between Pharmacies

1. The transfer of drugs listed in Schedule II to another pharmacy shall require the completion of a DEA Form 222, or its successor.

2. The transfer of drugs listed in Schedules III, IV, or V to another pharmacy shall require a written record, containing at a minimum, the drug name, strength, and dosage form; quantity of drug transferred; and the name, address, and DEA registration number of the recipient pharmacy.

C. Limitations. The total number of dosage units of all controlled dangerous substance distributed by a permittee during a calendar year shall not exceed 5 percent of the total number of dosage units of controlled dangerous substances procured by the permittee during the same calendar year. Should the permittee desire to exceed the 5 percent limitation, the permittee shall apply for a distributor's permit from the Louisiana Board of Wholesale Drug Distributors.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2111 (October 2003), effective January 1, 2004.

Chapter 27. Illegal Payments; Required Disclosures of Financial Interests

Subchapter A. General Information

§2701. Scope and Purpose of Chapter

A. Scope of Chapter. The rules of this Chapter interpret, implement, and provide for the enforcement of R.S. 37:1744 and R.S. 37:1745, or their successors, requiring disclosure of a pharmacist's financial interest in another health care provider to whom or to which the pharmacist refers a patient and prohibiting certain payments in return for referring or soliciting patients.

B. Declaration of Purpose; Interpretation and Application. Pharmacists owe a fiduciary duty to patients to exercise their professional judgment in the best interests of their patients in providing, furnishing, recommending, or referring patients for health care items or services. The purpose of these rules and the laws they implement is to prevent payments by or to a pharmacist as a financial incentive for the referral of patients to a pharmacist or other health care provider for healthcare services or items. These rules shall be interpreted, construed, and applied so as to give effect to such purposes and intent.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2112 (October 2003), effective January 1, 2004.

§2703. Definitions

A. As used in this Chapter, the following terms have the meaning ascribed to them by this Section.

Board—the Louisiana Board of Pharmacy.

Financial Interest—a significant ownership or *investment interest* established through debt, equity, or other means and held, directly or indirectly, by a *pharmacist* or a member of a *pharmacist*'s *immediate family*, or any form of direct or indirect *remuneration for referral*.

Group Practice—a group of two or more *pharmacists* and/or other health care providers legally organized as a general partnership, registered limited liability partnership, professional medical corporation, limited liability company, foundation, nonprofit corporation, faculty practice plan, or similar organization or association:

a. in which each *pharmacist* who is a member of the group provides substantially the full range of services which the *pharmacist* routinely provides;

b. for which substantially all of the services of the *pharmacists* who are members of the group are provided through the group and are billed under a billing number assigned to the group and amounts so received are treated as receipts of the group;

c. in which no pharmacist who is a member of the group directly or indirectly receives compensation based on the volume or value of *referrals* by the pharmacist, except *payment* of a share of the overall profits of the group, which may include a productivity bonus based on services personally performed or services incident to such personally performed services, so long as the share of profits or bonus is not determined in any manner which is directly related to the volume or value of *referrals* by such pharmacist; and

d. in the case of a faculty practice plan associated with a hospital, institution of higher education, or *pharmacy* school with an approved training program in which pharmacist members may provide a variety of different specialty services and provide professional services both within and outside the group, as well as perform other tasks such as research, solely with respect to services provided within such faculty practice plan.

Health Care Item—any substance, product, device, equipment, supplies, or other tangible good or article which is or may be used or useful in the provision of health care.

Health Care Provider—any *person*, partnership, corporation, or association licensed by a department, *board*, commission, or other agency of the state of Louisiana to provide, or which does in fact provide preventive, diagnostic, or therapeutic health care services or items.

Immediate Family—as respects a pharmacist, the pharmacist's spouse, children, parents, siblings, stepchildren, stepparents, in-laws, grandchildren and grandparents.

Investment Interest—a security issued by an entity, including, without limitation, shares in a corporation, interests in or units of a partnership or limited liability company, bonds, debentures, notes, or other debt instruments.

Payment—transfer or provision of money, goods, services, or anything of economic value.

Person—as defined in R.S. 37:1164(33) or its successor.

Pharmacist—any individual currently licensed by the *board* to engage in the practice of *pharmacy* in the state of Louisiana.

Pharmacy—any place where drugs are dispensed and *pharmacy* primary care is provided.

Referral—any direction, recommendation, or suggestion given by a health care provider to a patient, directly or indirectly, which is likely to determine, control, or influence the patient's choice of another health care provider for the provision of health care services or items.

Remuneration for Referral—any arrangement or scheme, involving any remuneration, directly or indirectly, in cash or in kind, between a pharmacist, or an *immediate family* member of such pharmacist, and another health care provider that is intended to induce *referrals* by the pharmacist to the health care provider or by the health care provider to the pharmacist, other than any amount paid by an employer to an employee who has a bona fide employment relationship with the employer, for employment in the furnishing of any *health care item* or service.

Significant Financial Interest—an ownership or *investment interest* shall be considered "significant," within the meaning of §2713, if such interest satisfies any of the following tests:

a. such interest, in dollar amount or value, represents 5 percent or more of the ownership or *investment interests* of the health care provider in which such interest is held; or

b. such interest represents 5 percent or more of the voting securities of the health care provider in which such interest is held.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2112 (October 2003), effective January 1, 2004.

Subchapter B. Illegal Payments

§2705. Prohibition of Payments for Referrals

A. A pharmacist or pharmacy shall not knowingly and willfully make, or offer to make, any payment, directly or indirectly, overtly or covertly, in cash or in kind, to induce another person to refer an individual to the pharmacist for the furnishing, or arranging for the furnishing, of any health care item or service.

B. A pharmacist or pharmacy shall not knowingly and willfully solicit, receive, or accept any payment, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient to a health care provider for the furnishing, or arranging for the furnishing, of any health care item or service.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004.

§2707. Prohibited Arrangements

A. Any arrangement or scheme, including cross-referral arrangements, which a pharmacist or pharmacy knows or should know has a principal purpose of ensuring or inducing referrals by the pharmacist to another health care provider, which, if made directly by the pharmacist or pharmacy would be a violation of §2713, shall constitute a violation of §2713.

AUTHORITY NOTE: Promulgated in accordance with R.S. 38:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004.

§2709. Exceptions

A. Proportionate Return on Investment. Payments or distributions by an entity representing a direct return on investment based upon a percentage of ownership, shall not be deemed a payment prohibited by R.S. 37:1745(B), or its successor, or §2705 of these regulations.

B. General Exceptions. Any payment, remuneration, practice, or arrangement which is not prohibited by or unlawful under §1128(b) of the Federal Social Security Act (Act), 42 U.S.C. §1320a-7b(b), or its successor, with respect to health care items or services for which payment may be made under Title XVIII or Title XIX of the Act, including those payments and practices sanctioned by the secretary of the United States Department of Health and Human Services, through the Office of the Inspector General, pursuant to §1128B(b)(3)(E) of the Act, through regulations promulgated at 42 CFR §1001.952, or its successor, shall not be deemed a payment prohibited by R.S. 37:1745(B), or its successor, or by §2705 of these rules with respect to health care items or services for which payment may be made by any patient or private or governmental payor.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004.

§2711. Effect of Violation

A. Any violation of, or failure of compliance with, the prohibitions and provision of §2705 of this Chapter shall be deemed a violation of the Pharmacy Practice Act, R.S. 37:1161 et seq., providing cause for the board to sanction a person culpable of such violation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004.

Subchapter C. Disclosure of Financial Interests in Third-Party Health Care Providers

§2713. Required Disclosure of Financial Interest

A. Mandatory Disclosure. A pharmacist or pharmacy shall not make any referral of a patient outside the pharmacist's or pharmacy's group practice for the provision of health care items or services by another health care provider in which the referring pharmacist has a financial interest, unless, in advance of any such referral, the referring pharmacist or pharmacy discloses to the patient, in accordance with §2713 of this Chapter, the existence and nature of such financial interest.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2113 (October 2003), effective January 1, 2004.

§2715. Form of Disclosure

A. Required Contents. The disclosure required by §2713 of this Chapter shall be made in writing, shall be furnished to the patient, or the patient's authorized representative, prior to or at the time of making the referral, and shall include:

1. the pharmacist's or pharmacy's name, address, and telephone number;

2. the name and address of the health care provider to whom the patient is being referred by the pharmacist or pharmacy;

3. the nature of the items or services which the patient is to receive from the health care provider to which the patient is being referred; and

4. the existence and nature of the pharmacist's or pharmacy's financial interest in the health care provider to which the patient is being referred.

B. Permissible Contents. The form of disclosure required by §2713 of this Chapter may include a signed acknowledgment by the patient or the patient's authorized representative that the required disclosure has been given.

C. Approved Form. Notice to a patient given substantially in the form of Disclosure of Financial Interest prescribed in §2719 of this rule shall be presumptively deemed to satisfy the disclosure requirements of this Subchapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2113 (October 2003), effective January 1, 2004.

§2717. Effect of Violation; Sanctions

A. Effect of Violation. Any violation of, or failure of compliance with, the prohibitions and provision of §2713 of this Chapter shall be deemed a violation of the Pharmacy Practice Act, R.S. 37:1161 et seq., providing cause for the board to sanction a pharmacist or pharmacy culpable of such violation.

B. Administrative Sanctions. In addition to the sanctions provided for by R.S. 37:1241, upon proof of violation of §2713 by a pharmacist or pharmacy, the board may order that all or any portion of any amounts paid by a patient, and/or by any third-party payor on behalf of a patient, for health care items or services furnished upon a referral by the pharmacist or pharmacy in violation of §2713, be refunded by the pharmacist or pharmacy to such patient and/or third-party payor, together with legal interest on such payments at the rate prescribed by law calculated from the date on which any such payment was made by the patient and/or third-party payors.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2114 (October 2003), effective January 1, 2004.

§2719. Disclosure of Financial Interest

[Name of Pharmacist/Group]
[Address]
[Telephone Number]

DISCLOSURE OF FINANCIAL INTEREST
As Required by R.S. 37:1744 and LAC 46:LIII.613-615

TO:_____ DATE:_____

_____
(Name of Patient to Be Referred)

_____
(Patient Address)

Louisiana law requires pharmacists and other health care providers to make certain disclosures to a patient when they refer a patient to another health care provider or facility in which the pharmacist has a significant financial interest. [I am/we are] referring you, or the named patient for whom you are legal representative, to:

_____
(Name and Address of Provider to Whom Patient is Referred)

to obtain the following health care services, products, or items:

_____
(Purpose of the Referral)

[I/we] have a financial interest in the health care provider to whom we are referring you, the nature and extent of which are as follows:

_____
_____

PATIENT ACKNOWLEDGEMENT

I, the above-named patient, or legal representative of such patient, hereby acknowledge receipt, on the date indicated and prior to the described referral, of a copy of the foregoing Disclosure of Financial Interest.

_____
Signature of Patient or Patient's Representative)

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2114 (October 2003), effective January 1, 2004.

Chapter 29. Severability

§2901. Severability

A. In the event any rule, sentence, clause, or phrase or any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof, and such remaining rules or portions thereof shall remain of full force and effect, as if such rule or portions thereof so determined, declared, or adjudged invalid or unconstitutional were not originally a part hereof. It is the intent of the Louisiana Board of Pharmacy to establish rules and regulations that are constitutional and enforceable so as to safeguard the health, safety, and welfare of the people of the state.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2114 (October 2003), effective January 1, 2004.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LIII. Pharmacists
Index